Mood and Anxiety Symptomatology in Adults with Insulin-Dependent Diabetes Mellitus Using Intensive Management Regimens

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Abstract

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Diabetes mellitus (DM) is one of the most prevalent health concerns present today. However, only a modest literature has examined diabetes and its related medical complications as it relates to psychological well-being. Findings suggest that individuals with DM have higher rates of mood and anxiety symptoms. However, most studies have used combined samples of individuals with Type I and Type II DM despite these disorders being different etiologically. No studies to date have attempted to (a) examine posttraumatic stress reactions in relation to hypoglycemic episodes, or (b) characterize mood and anxiety, particularly fear of hypoglycemia (FH), within individuals with Type I DM using different intensive methods of insulin administration. The present study investigated the prevalence of mood and anxiety symptomatology, including hypoglycemic fear and posttraumatic stress, among individuals with Type I DM using different intensive management regimens in an attempt to further characterize the nature of mood and anxiety in this unique population. Planned and exploratory multiple regression analyses yielded overall non-significant findings. A consistent trend displayed was that individuals using self-injecting techniques scored higher on measures of FH, anxiety, posttraumatic stress, and glycemic control. Insulin shot users reported statistically higher glycosylated hemoglobin levels and behavior symptoms of FH. Results suggest that as one ages, anxiety significantly decreases, and glycemic control

significantly improves, and that women report significantly higher levels of overall FH than men. A common trend was that women reported higher levels of mood and anxiety, and poorer glycemic control than men. One exception was with regards to posttraumatic stress symptoms and diagnostic criteria. Overall, this study accomplished several of its primary goals. The nature of mood and anxiety symptomatology and relative differences among Type I individuals using different methods of insulin administration were revealed. The impact of method of administration and hypoglycemic experiences on FH were systematically investigated. Finally, hypoglycemia-related posttraumatic stress was examined and revealed that 1 out of 4 individuals meet diagnostic criteria for PTSD. This provides evidence that for a subset of individuals with Type I diabetes, the medical sequelae associated with hypoglycemic states is sufficient enough to qualify as a traumatic event.

CHAPTER 1: INTRODUCTION

Overview of Diabetes Mellitus (DM) and its Complications

Diabetes mellitus (DM) is the most common endocrine disorder, and is characterized by the failure of the body to produce properly or use insulin (Leese, 1992). Insulin is a hormone produced in the pancreas that allows for transport of glucose (sugar) from the blood to all types of cells in the body (American Diabetes Association [ADA], 2001). Poor production or use of insulin by the body results in a low absorption of glucose by the body's cells, which use the glucose for energy, and the liver, which stores it (Clayman, 1994). Since the body is unable to use glucose because of the lack of insulin, low glucose absorption results in abnormally high levels of blood glucose (BG). This chronic disorder affects the metabolism of carbohydrates, protein, and fat, and can alter the metabolic balance of the body's electrolytes and water (Deary & Frier, 1995).

There are approximately 15.7 million people (5.9% of the general population) in the United States alone that have diabetes. Only an estimated 10.3 million people have been formally diagnosed. Therefore, approximately 5.4 million of these individuals with diabetes are unaware that they have the disease (ADA, 2001; Kenny, Aubert, & Geiss, 1995). Roughly 798,000 individuals are diagnosed with diabetes each year, averaging 2,200 new cases of diabetes each day (ADA, 2001). Diabetes and its subsequent complications are the third leading cause of death in the United States, and the disease has no cure (Strauss, 1996).

Many individuals first become aware of their diabetes at the onset of life-threatening complications. There are many long-term and short-term medical

complications associated with the disease (Leese, 1992). Many of the long-term life-threatening complications occur 15 to 20 years after the onset of the disease (ADA, 2001). The long-term medical complications of DM include retinopathy (an eye disorder that causes blindness), renal disease, peripheral neuropathy (nerve disease), and heart disease/stroke (Leese, 1992). Diabetic retinopathy is characterized by abnormalities of small blood vessels in the retina caused by DM. The end result is the weakening or leakage of these blood vessels, and subsequent bleeding into the fluid-filled center of the eye (ADA, 2001; Clayman, 1994). Diabetic retinopathy is the leading cause of new blindness in individuals between 20-74 years of age, with approximately 12,000 to 24,000 individuals becoming blind due to complications of diabetes each year. DM is responsible for 8% of legal blindness in the United States (ADA, 2001).

Nephropathy (kidney disease) is a common complication of DM. Diabetic nephropathy is a progressive disease, and is the leading cause for end-stage renal disease (ESRD) (Leese, 1992). Diabetic nephropathy is characterized by damaged and leaky blood vessels in the kidneys. Eventually, the entire filtration system becomes destroyed, and the kidneys fail to function. This is called end-stage renal disease (ESRD). Approximately 40% of ESRD is due to DM complications. Individuals with Type I diabetes are 12 times more likely to develop ESRD than those with Type II DM (ADA, 2001).

Peripheral neuropathy occurs when there is damage to the peripheral nerves that lead from the brain and spinal cord out to the rest of the body. Symptoms include tingling and numbness of the extremities. Unawareness of injury or infection to the

extremities, as well as muscular atrophy, can result in the need for amputation. Approximately 60-70% of individuals with DM have some form of nerve damage. DM is the most frequent cause of non-traumatic lower limb amputations (Leese, 1992), with individuals with DM being 15-40 times at greater risk for leg amputation (ADA, 2001).

People with DM run a higher risk of developing atherosclerosis, along with its risks of high blood pressure, heart attack, and stroke (ADA, 2001; Leese, 1992). Heart disease is present in 75% of diabetes-related deaths, and individuals with DM are 2 to 4 times more likely to suffer a stroke (ADA, 2001).

In a non-diabetic person, blood glucose (BG) concentrations are maintained within the approximate range of 70 mg/dl to 150 mg/dl (Gonder-Frederick, Cox, Bobbitt, & Pennebaker, 1989). Many of the aforementioned medical complications of DM are due to the long-term consequences of hyperglycemia. Hyperglycemia (high blood sugar) occurs when the body has insufficient or improperly used insulin. The symptoms of hyperglycemia include high blood glucose (BG) levels, high levels of glucose in the urine, increased thirst, and frequent urination. Failure to treat hyperglycemia can result in the life-threatening condition of diabetic ketoacidosis (DKA). DKA occurs when insufficient insulin is produced or used, which results in the body being unable to use glucose for fuel. As compensation, the body breaks down stored fats to utilize for fuel. The breakdown of fat into fuel produces ketones, which are acids that can accumulate in the blood. Ketones are highly toxic to the body, and ketone build up can result in coma and death (ADA, 2001).

Hypoglycemia is the result of low blood sugar levels, and is generally considered to exist when BG levels fall below 50 mg/dl (Hall, Stickney, & Beresford, 1986). Although hypoglycemia can occur among all individuals with DM, it is more common among individuals treated with insulin (Deary & Frier, 1995). The common causes of hypoglycemia are an excessive dose of insulin in relation to ingestion of food and exercise (Deary & Frier, 1995). The symptoms of hypoglycemia can be classified into autonomic and neuroglycopenic symptoms (Cryer, Fisher, & Shamoon, 1994; Deary & Frier, 1995). Neuroglycopenic symptoms are the result of direct glucose deprivation of the brain (Cryer et al., 1994). The cognitive and behavioral symptoms include drowsiness, incoordination, speech difficulty, poor concentration, confusion, seizure, coma, and potential death (Cryer et al., 1994; Deary & Frier, 1995). Autonomic symptoms are the result of perceptions related to physiological and hormonal changes caused by the autonomic nervous system. These symptoms include trembling/shakiness, tachycardia, hunger, sweating, tingling, and nervousness/anxiety (Cryer et al., 1994; Deary & Frier, 1995).

Hypoglycemic episodes can range from mild to severe. Mild episodes are categorized typically as symptoms that the individual can self-detect (symptom awareness), and ameliorate through ingestion of glucose. There are normal fluctuations of BG throughout the day due to variations in amount of exercise and food consumption. Therefore, mild forms of hypoglycemia can occur frequently (Cryer et al., 1994). Risk of mild hypoglycemic states is especially high during nocturnal hours. One study

approximated the number of mild-to-moderate hypoglycemic episodes for a sample to be 1.8 episodes per week (Pramming, Thorsteinsson, Bendtson, & Binder, 1991).

Severe hypoglycemic episodes are more life threatening, and require external assistance. Severe episodes may result in coma or morbidity, because the brain is being denied its continuous supply of glucose (Cryer et al., 1994; Deary & Frier, 1995). During these episodes, cognitive function deteriorates. The individual becomes unable to self-regulate BG levels, and becomes dependent on others to supply fast-acting glucagons or call for emergency assistance (Cryer et al., 1994; Deary & Frier, 1995). The frequency of severe hypoglycemia among individuals with IDDM ranges from 4.5 to 44 % of patients per year, with approximately 10-26% of patients experiencing one hypoglycemic episode per year (Cryer et al., 1994; Tattersall, 1993).

Classification, Diagnoses, and Treatment of Diabetes Mellitus (DM)

DM is delineated into two types, Type I and II. The types are separate metabolic disorders with different etiologies (Deary & Frier, 1995). Type I DM, also known as insulin-dependent diabetes mellitus (IDDM), was classified formerly as juvenile-onset diabetes. This type is an autoimmune disease in which the body fails to produce enough or any insulin. Failure to produce sufficient insulin is commonly caused by a defect or damage to the insulin-producing cells (beta cells) of the pancreas (Clayman, 1994). This type of Type I DM is known as immune-mediated diabetes. The other type of Type I diabetes, idiopathic Type I, has no known cause (ADA, 2001). Type I is the rare form of the disease and accounts for approximately 5 to 10 percent of all diabetes cases (ADA, 2001). Type I is characterized by an early onset, and is commonly first diagnosed in

adolescence or by young adulthood. However, peak incidence occurs during puberty. Type I tends to run in families. Identical twins of Type I DM individuals have a 25-50% chance of developing Type I DM. Siblings of children with Type I DM have a 10% chance of developing DM by age 50 (ADA, 2001). Also, there is a higher incidence among Caucasians (ADA, 2001). Exogenous insulin can be introduced through different methods of administration, and is required daily to maintain life functioning (Rubin & Peyrot, 2001). Individuals with Type I DM are said to be insulin-dependent.

Type II DM is the more common form of diabetes, and is also known as non-insulin dependent diabetes mellitus (NIDDM). However, it may worsen and become insulin-dependent. Type II DM results from insulin resistance. In this condition, the body fails to use the insulin that is produced effectively, because the tissues and cells have become less sensitive to the hormone. Specifically, over time the body becomes insensitive to insulin that it produces. In addition to these changes, insulin production decreases resulting in insulin deficiency (ADA, 2001; Rubin & Peyrot, 2001). Approximately 90 to 95% of individuals with DM have Type II, and nearly one third are unaware that they have the disease (ADA, 2001). Onset of Type II DM occurs on average after the age of 40, and many individuals with DM are unaware of their condition until serious medical complications arise (ADA, 2001). Sedentary lifestyle and obesity are associated with the onset of Type II DM (ADA, 2001). Other risk factors for Type II DM include having a relative with DM, being an ethnic minority, and women who have had gestational diabetes (ADA, 2001). Control of Type II DM can be accomplished

through a healthy diet and exercise, and if necessary, oral hypoglycemic medications (ADA, 2001). Eventually, some individuals require insulin.

Regardless of whether an individual has Type I or II DM, glycemic control is essential to effective diabetes management. Monitoring of BG levels is the main tool that individuals have to check their diabetes control (ADA, 2001). Individuals monitor their BG by drawing a droplet of blood from their finger using a lancet, and placing the blood on a BG meter. Glucometers are small, portable computerized machines that calculate the current level of BG. Depending on the BG reading, the individual can take action to maintain BG levels. The goal of BG monitoring is to have tight control by maintaining BG levels within normal non-diabetic ranges. For individuals that require insulin to manage their diabetes, BG monitoring should be done approximately 4 or more times a day, especially prior to introducing exogenous insulin to their system. Glycemic control can also be measured via glycosylated hemoglobin levels (GHb). Glycosylated hemoglobin is a blood assay test that measures average BG level over the past 3 to 4 months (ADA, 2001).

There are two primary methods of intensive exogenous insulin administration: multiple daily injection therapy and insulin pump (ADA, 2001). In multiple daily injection therapy, the individual injects three or more insulin shots per day. Typically, the individual administers a shot of short-duration insulin prior to each meal, and a shot of intermediate or long-acting insulin in the morning and at bedtime (ADA, 2001). Continuous subcutaneous insulin infusion (CSII), or insulin pump therapy, is the other method of administration. This technique employs a small portable pump filled with

insulin attached to a subcutaneous infusion site by a small plastic catheter (Brink & Stewart, 1986). The catheter is inserted just under the skin, usually in the abdomen. The pump is battery operated and can be programmed to deliver a continuous supply of short-acting insulin (basal rate) 24 hours a day. Prior to meals, the individual programs the pump to deliver a bolus amount of insulin matched to the amount of food that will be consumed. The goal of the insulin pump is to mimic the natural delivery of insulin found in non-diabetic individuals. CSII therapy has been associated with increased flexibility and lifestyle advantages (Wolf, Jacober, Wolf, Cornell, & J.C. Floyd, 1989) and improved glycemic control (Champion, Sheperd, Rodger, & Dupre, 1980). Data on the prevalence of individuals with DM that use insulin pumps has not been published.

The Diabetes Control and Complications Trial (DCCT, 1993) was a multicenter, randomized clinical trial designed to compare intensive and conventional diabetes therapy on effectiveness for controlling the progression of vascular and neurological complications of IDDM. Results showed that the intensive therapy regimen, defined as either (a) three or more daily injections of insulin, or (b) treatment with an insulin pump, effectively delayed the onset and slowed the progression of diabetic neuropathy, nephropathy, and retinopathy by a range of 34-76%. These results suggested that intensive therapy as compared to the conventional therapy was significantly better at preventing and/or slowing the progression or onset of long-term microvascular and neurological complications associated with DM. Additionally, intensive therapy showed improved glycemic control as measured by glycosylated hemoglobin. However, two adverse effects were also associated with intensive insulin therapy. Specifically,

individuals with tighter control of their BG levels on average gained 10 lbs more than those on conventional insulin therapy, and were 3 times more likely to have a severe hypoglycemic episode. Despite the increased risk of hypoglycemia in the intensive therapy condition, there were no significant differences between the conventional and intensive therapy groups with regard to acute medical complications directly related to a severe hypoglycemic state. Specifically, the two conditions did not differ with regard to deaths, myocardial infarctions, or strokes directly attributable to hypoglycemia. Additionally, there were no differences in major accidents requiring hospitalization as a result of severe hypoglycemia. Therefore, the DCCT concluded that the benefits associated with intensive therapy outweighed the risk of severe hypoglycemia, because there were no significant differences between the two conditions with regards to severe hypoglycemic complications.

One shortcoming of the DCCT study is that no distinctions were made within the intensive therapy regimen group regarding differences that may be related to regimen choice. Specifically, the intensive regimen condition was a combined sample of individuals who either utilized multiple daily self-injections or insulin pumps. No within group comparisons were made between these two intensive management regimens to clarify whether there were any systematic differences related to choice of intensive regimen that may have influenced the outcome of the study.

Psychopathology and DM

There has been a burgeoning of interest in psychological responses to chronic illness, and to diabetes in particular (Gill, 1991). The focus of much of the psychological

literature with regards to DM has focused on prevalence of disorders. However, there has been increased attention given to how psychological issues affect DM self-management, as well as the psychological consequences of having a DM diagnosis (Rubin & Peyrot, 2001). Diabetes carries with it a considerable amount of stress. Individuals with DM must self-manage their diabetes treatment regimen constantly. For example, individuals with DM must be more vigilant than non-diabetic persons with regards to normal daily activities such as eating, sleeping, and exercise. In addition, individuals with DM must monitor BG levels and medication continually. The goal of the individual with DM is to strike a balance in their BG range in order to avoid the medical complications associated with hyperglycemia and the acute complications of hypoglycemia (Rubin & Peyrot, 2001). Being too far at the polar opposites of the hypo/hyperglycemia state has severe consequences. The constant stress of maintaining tight glycemic control can result in two types of psychological distress (a) subclinical emotional distress, and (b) diagnosable psychological disorders (Rubin & Peyrot, 2001). Additionally, psychiatric conditions can occur independently without being a consequence of DM. Unfortunately, the characterization of psychological distress within a DM population is still scant in the literature.

It has been shown that individuals with DM have a disproportionately higher rate of psychiatric disorders (Rubin & Peyrot, 2001), with affective and anxiety disorders being more commonly diagnosed than in the general population (de Mont-Marin, Hardy, Lepine, Halfon, & Feline, 1995; Friedman, Vila, Timsit, Boitard, & Mouren-Simeoni, 1998; Gavard, Lustman, & Clouse, 1993; Popkin, Callies, Lentz, Colon, & Sutherland,

1988; Weyerer, Hewer, Pfeifer-Kurda, & Dilling, 1989). In a study by Lustman, Griffith, Clouse, & Cryer (1986), 71% of a Type I and II DM sample had a lifetime history of at least one psychiatric disorder. Major depressive disorder (MDD) and generalized anxiety disorder (GAD) occurred at the highest rates, 32.4 % and 40.9 % respectively, and were 6-7 times more likely to occur than in an observed control population. Additionally, the authors reported higher rates of psychiatric illness in their population than in other studies of patients with serious medical illnesses (e.g., cancer, regional enteritis, and end stage renal disease). The authors suggested that generalization of their prevalence data be interpreted with caution since their sample was most likely more physically ill than a general practice population of DM. In contrast to these findings, another study that examined psychiatric disorders using the NIMH Diagnostic Interview Scale (DIS) among eight chronic medical conditions (e.g., chronic lung disease, heart disease, hypertension, arthritis, physical handicap, cancer, neurological disorder, and diabetes), showed less conclusive results (Wells, Golding, & Burnam, 1988). Specifically, these findings indicated that although affective and anxiety disorders were more common among persons with chronic medical conditions in general, individuals with DM fared better psychologically compared to other medical conditions. Nonetheless, the researchers still cited a substantial lifetime prevalence rate of 34 % for any psychiatric disorder for their DM sample.

More recently, in a French sample of Type I and II DM inpatients, 52 % presented with at least one lifetime psychiatric disorder, and 41.3 % presented with a diagnosis within the past 6 months (de Mont-Marin et al., 1995). In this sample,

affective and anxiety disorders represented 83 % of the psychiatric diagnoses. Another French sample, specific to IDDM outpatients, showed rates of anxiety and depressive disorders not otherwise specified at 44 % and 41.5 %, respectively (Friedman et al., 1998). For this sample, rates for simple phobia, social phobia, and agoraphobia were 26.8 %, 24.6 %, and 14.6 %, respectively. Interestingly, current social phobia, dysthymia, and depression NOS were associated with impaired glycemic control as measured by glycosylated hemoglobin.

In an epidemiological study of depression in individuals with Type I and II DM, findings revealed that depression was 3-4 times more prevalent in this population than in the general population (Gavard et al., 1993). These results suggest that 15-20 %, or approximately 1 in 5 individuals with either IDDM or NIDDM are afflicted with depression. Furthermore, approximately 40 % of individuals with DM have significantly elevated levels of depressive symptomatology, but are not clinically depressed.

Given the elevated prevalence of depression among individuals with DM, a few studies have attempted to characterize further the disorder. For example, in a study by Peyrot & Rubin (1997), elevated depressive symptoms varied according to two factors: (a) non-diabetes specific (generic) factors, and (b) diabetes-related factors. The researchers found higher rates of depression among women, individuals who were unmarried, and those with less education. Higher rates of depression were also found in individuals with three or more diabetes medical complications. Other studies have examined the relationship between social problems and depression in individuals with DM (Roy, Collier, & Roy, 1994; Wilkinson et al., 1988). Specifically, Roy, Collier, &

Roy (1994) found that social problems are reported more often among individuals with IDDM. Also, Wilkinson et al (1988) found that individuals reporting major social problems had significantly higher levels of psychiatric morbidity. Other studies have investigated the influence of depression on glycemic control and other adherence measures. Specifically, a few studies have found that individuals with DM and a history of depression showed significantly worse glycemic control as measured through glycosylated hemoglobin (Ciechanowski, Katon, & Russo, 2000; de Groot, Jacobson, Samson, & Welch, 1999; Friedman et al., 1998). However, contradictory findings do exist (Roy et al., 1994).

The course of depression in the DM population is chronic and severe (Lustman, Griffith, Freedland, & Clouse, 1997c; Peyrot & Rubin, 1999; Rubin & Peyrot, 2001), and the presence of depression in individuals with DM may significantly worsen the course of both disorders (Goodnick, 1997). A few studies have examined the influence of psychopharmacology and psychotherapy on the treatment of depression in this population. The results seem promising with improvement towards a reduction in depressive symptoms, as well as improved glycemic control (Goodnick, Henry, & Buki, 1995; Lustman, Freedland, Griffith, & Clouse, 1998; Lustman et al., 1997b; Rubin & Peyrot, 2001).

Although the prevalence literature indicates increased anxiety among individuals with DM compared to the general population, it has not been examined as systematically as depression. Some studies suggest that lifetime- and recent prevalence rates of anxiety disorders may be just as or more common than depressive disorders among individuals

with DM (Peyrot & Rubin, 1997; Wells, Golding, & Burnam, 1989). In the study by Peyrot & Rubin (1997), their findings suggest that individuals with diabetes may suffer from high anxiety levels as frequently as they do depression. Similar to their earlier findings with depression, the researchers found that women and those with less education were more likely to report clinically significant anxiety. Also, the presence of diabetes medical complications was significantly associated with increased anxiety. In the Wells, Golding, & Burnam (1989) study, individuals with diabetes were more than twice as likely to have an anxiety disorder than a depressive disorder. Yet despite these findings, less empirical attention has been given to anxiety.

Earlier literature hypothesized that the presence of anxiety in individuals with DM may jeopardize glycemic stability (Lustman, 1988). It was believed that physiological responses associated with stress, (e.g., increased heart rate, high amplitude GSR, vasoconstriction, etc.), and its metabolic consequences may yield non-volitional increases in blood glucose. Simply, it was thought that stress could result in a hyperglycemic event in the individual with diabetes. Tests of this hypothesis have been inconclusive (Lustman, 1988). However, there is paucity of information on the topic, and there is some preliminary evidence suggesting that anxiety has a negligible effect on glycemic control (Lustman, 1988; Rubin & Peyrot, 2001).

Several studies have found high rates of generalized anxiety disorder among the DM population (de Mont-Marin et al., 1995; Lustman, 1988; Lustman et al., 1986; Popkin et al., 1988). Estimates suggest that GAD may be 6 times more likely to occur in the diabetes population than general population (Lustman, 1988). There are

physiological responses associated with anxiety, (e.g., increased heart rate, sweating, shakiness), that may mimic the physical symptoms of either a hypo-or hyperglycemic state. In turn, individuals with DM may misinterpret the physical symptoms associated with a hypo-or hyperglycemic state as being indicative of an anxiety state rather than an artifact of their BG level. This suggests that for these individuals with DM, they may have a reduced ability to differentiate between anxiety and symptoms related to their BG level. Therefore, anxiety disorders in an individual with DM may be more readily diagnosable by a clinician when the anxiety symptoms are based more on emotional or behavioral (e.g., persistent fears, worries, obsessions, compulsions) rather than physical symptoms alone (Jacobson, 1996). This phenomenon may strongly be associated with why generalized anxiety disorder, a disorder characterized by persistent and excessive worry, is common among individuals with DM. However, this trend has not been studied systematically.

The literature and prevalence findings suggest that anxiety is a common occurrence among individuals with DM. Anxiety disorders represent exaggerated emotional responses to fear (Rubin & Peyrot, 2001). Most of the studies conducted on anxiety have focused on distinct psychiatric diagnoses. However, none have assessed for posttraumatic stress. Nonetheless, there have been some attempts to further qualify types of anxiety or fear that individuals with DM experience. Most notably is the research on diabetes related fear of hypoglycemia.

Fear of Hypoglycemia

The therapeutic goal of glycemic control is to normalize BG ranges. However, for the population with IDDM, tight glycemic control increases the risk of hypoglycemia (Irvine, Cox, & Gonder-Frederick, 1994). The consequences of a hypoglycemic episode are physically aversive, create negative mood states, and can be potentially life threatening (Gold, MacLeod, Frier, & Deary, 1995; Gonder-Frederick et al., 1989; Polonsky, Davis, Jacobson, & Anderson, 1992; Taylor & Rachman, 1988). The physical symptoms are uncomfortable, and individuals with DM are fearful of these feelings. The social consequences of a hypoglycemic episode may lead to embarrassment or job loss (Cox, Irvine, Gonder-Frederick, Nowacek, & Butterfield, 1987). Furthermore, many individuals with DM are knowledgeable that the symptoms of hypoglycemia may signal coma or potential death (Cox et al., 1987; Strauss, 1996). In some, personal or vicarious experiences with hypoglycemia may result in phobic avoidance reactions to low BG. For example, some individuals will compromise their glycemic control by running their insulin levels lower in an attempt to avoid these feelings by keeping BG levels high (Surwit, Scovern, & Feinglos, 1982), or overtreat early signs of hypoglycemia (Cox et al., 1987). For these individuals, they are placing themselves at increased risk for the long term medical complications associated with hyperglycemia.

Given the aversive nature of hypoglycemia and its frequent occurrence for many, it is not surprising that fear of hypoglycemia along with its behavioral and cognitive sequelae constitute a continual threat among many individuals with IDDM (Deary & Frier, 1995; Polonsky et al., 1992). Recently, researchers have given more attention to

the phenomenon of fear of hypoglycemia (FH). There have been several studies that have examined the concept of FH, as well as the scale developed specifically to examine FH, the Hypoglycemic Fear Survey (HFS) (Cox et al. 1987).

In a 1987 study by Cox et al., the authors developed the Hypoglycemic Fear Survey (HFS) as a research and clinical tool measuring the degree of fear experienced in relation to hypoglycemia. The rationale for the development of the instrument was that an excessive fear of hypoglycemia may produce phobic reactions in some individuals with DM. In turn, this fear may interfere with diabetes self-management and jeopardize physical well-being. The primary objective of this validation study was to determine the scaling and psychometric properties of the original Hypoglycemic Fear Survey (HFS), as well as its relationship to metabolic control for a sample of individuals with IDDM. The HFS is a 27-item measure of FH divided into two subscales: Behavior (HFS-B) and Worry (HFS-W). The HFS provides a total score for each of these domains: how much the individual worries about hypoglycemia, and any subsequent behaviors associated with the fear of hypoglycemia. Findings from the validation study indicated that the HFS has good psychometric properties (Cox et al., 1987). Specifically, the HFS showed high internal consistency, and good temporal stability. The test-retest validity was demonstrated by two samples, one American and one British (Cox et al., 1987). Furthermore, the HFS was useful for predicting poor metabolic control (Cox et al., 1987). The authors suggested that the HFS may be able to identify individuals likely to maintain high BG levels, thus leading to better understanding for the reasons for poor glycemic

control. Also, the authors suggested that the inability to anticipate hypoglycemic episodes was a primary fear of hypoglycemia.

Another study examined FH in individuals with Type I and II DM requiring insulin (Polonsky et al., 1992). The goals of the study were to examine whether FH was associated with (a) higher levels of trait anxiety and general fearfulness, (b) difficulty in differentiating between anxiety and hypoglycemia symptoms, and (c) past experiences with hypoglycemia. The researchers found that individuals with Type I IDDM experience significantly more FH than their Type II counterparts. For both Type I and II individuals, higher scores on the HFS Worry subscale were associated with higher levels of trait anxiety and fear, whereas higher scores on the Behavior subscale were indicative of higher fear levels only. For Type I participants, the Worry subscale was associated with past hypoglycemic episodes, and difficulty discriminating hypoglycemic and anxiety symptoms. The researchers suggested two possible sequences to explain FH: (a) FH may result from recurrent hypoglycemic episodes which produce a diminished capacity to discriminate hypoglycemia symptomatology. This decreased symptom awareness leads to more chronic and pervasive anxiety and fear, or (b) FH may be a combination of chronic fear and anxiety with recurrent hypoglycemic episodes. This leads to a reduced capacity to distinguish between anxiety and hypoglycemia. Specifically, the chronically anxious individual may confuse signs of hypoglycemia as a sign of anxiety.

Another study of individuals with Type I DM examined the relationship of FH to psychological symptoms, perceived stress, risk of hypoglycemia, and glycemic control

(Irvine, Cox, & Gonder-Frederick, 1992). In this study, participants were administered the HFS, the Hopkins Symptom Checklist-90 (SCL-90), the Perceived Stress Scale (PSS), and the Hypoglycemic Experiences Questionnaire (HEQ). The results indicated that both subscales of the HFS correlated with the Phobic Anxiety Subscale and Total Symptoms Scale scores of the SCL-90. The HFS Worry subscale was significantly related to the PSS indicating that higher levels of worry about hypoglycemia were associated with higher levels of perceived stress. These findings suggest that individuals with more psychological symptoms tend to experience higher levels of fear of hypoglycemia.

Interestingly, there was a significant association between frequency of hypoglycemic experiences in the past year and the HFS Behavior subscale, but not the Worry subscale. This suggests that the adversity of these past hypoglycemic episodes may motivate individuals to avoid future episodes via their behavior. Glycemic control, as measured by glycosylated hemoglobin, was unrelated to both HFS subscales. However, daily BG variability, as measured by self-monitoring, was related to the HFS Worry subscale. Specifically, individuals with lower mean daily BG and higher BG variability were more fearful of hypoglycemia. This is most likely because these individuals are at higher risk for hypoglycemia, and therefore worry more about it.

In summary, these studies show (a) the validity and reliability of the HFS, and (b) that that fear of hypoglycemia is quite complex. FH may have adverse affects on adherence, which in turn directly influences future risk of complications. Also, worry and behavior to avoid hypoglycemia seem to be associated with psychological symptoms

and perceived stress. Although these studies have focused on mixed samples of IDDM participants, one shortcoming is that none of the studies specified method of administration of insulin. Specifically, none of these studies have examined any potential systematic differences that may be a result of which intensive administration method is utilized. One potential finding may be that continuous subcutaneous insulin infusion (CSII), or insulin pump therapy, may produce more fear of hypoglycemia compared to the self-injecting method, because of the increased risk of hypoglycemia with this particular intensive therapy method. However, this issue has yet to be examined systematically.

Posttraumatic Stress Disorder (PTSD) & Posttraumatic Stress (PTS)

Posttraumatic Stress Disorder (PTSD) is an emotional disorder precipitated by a traumatic event. The fourth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV; American Psychiatric Association, 1994) delineates that there are 4 criteria that are the foundation for PTSD. The first criteria and essential feature describes the setting event for PTSD as an exposure to a traumatic event, which is either a perceived or actual threat to self or other during which one feels fear, helplessness, or horror. Reexperiencing is the second criteria necessary for a diagnosis of PTSD. After a traumatic event, victims often reexperience the event through recurrent and intrusive recollections, nightmares, intense psychological distress, or physiological reactions. The third criteria is persistent avoidance of stimuli associated with the trauma and numbing of general responsiveness. Individuals will avoid stimuli that remind them of the trauma and display a characteristic numbing of their emotional responsiveness. Examples of

avoidance and numbing include (a) deliberate efforts to avoid thoughts, feelings, or conversations about the event, (b) avoiding certain activities or situations, (c) memory loss for aspects of the trauma, (d) feelings of detachment and reduced ability to feel emotions, and (e) a sense of foreshortened future. The fourth criteria involves persistent symptoms of increased arousal.

Symptoms must be present for more than 1 month and must result in clinically significant distress or impairment in social, occupational, or other important areas of functioning to receive the diagnosis. Prevalence studies suggest that between 1 % to 14 % of the general population have met criteria for PTSD (American Psychiatric Association, 1994).

Increased attention has recently been given to the concept of Posttraumatic Stress (PTS) symptoms in individuals with medical complications. The rationale is that either receiving a diagnosis and/or the sequelae of medical complications related to the diagnosis may be sufficient to meet the DSM-IV criteria of a traumatic event. Specifically, receiving a medical diagnosis and/or its related complications may serve as a threatening event that is traumatic to the individual. Subsequently, the individual may respond to his/her medical threat with feelings of fear and helplessness.

The most extensive line of research in this area has been conducted on individuals with cancer (Mundy et al., 2000; Neel, 2000; Pitman et al., 2001; Smith, Redd, Peyser, & Vogl, 1999; Widows, Jacobsen, & Fields, 2000). Most studies have shown that individuals with a diagnosis of cancer have elevated rates of PTS symptoms. Other studies have shown that vicarious traumatization can occur among parents and other

family members of cancer patients (Best, Streisand, Catania, & Kazak, 2001; Boyer et al., 2002) and may affect long-term psychological adjustment (Barakat, Kazak, Gallagher, Meeske, & Stuber, 2000; Erickson & Steiner, 2001). Additional studies have demonstrated elevated PTS symptoms in other non-cancer related medical disorders. These medical conditions include pediatric spinal cord injury (Boyer, Tollen, & Kafkalas, 1998; Boyer, Knolls, Kafkalas, Tollen, & Swartz, 2000), subarachnoid hemorrhage (Berry, 1998), and myocardial infarction (Doerfler, Pbert, & DeCosimo, 1994).

The examination of PTS symptoms in the health field is still in its initial stages. However, these studies demonstrate that health-related complications and medical diagnoses are sufficient to qualify as traumatic events in some individuals. Preliminary research on the topic suggests that fear of hypoglycemia (FH) often results in increased and chronic anxiety among many individuals with DM. Despite evidence that individuals who experience increased FH also experience elevated levels of perceived stress and anxiety, no studies to date have examined the impact of hypoglycemic episodes related to DM as a potential source of PTS symptoms. Specifically, no research has examined whether FH and the risks associated with hypoglycemia result in posttraumatic stress. Given the prevalence of DM, as well as the negative physical, social, and emotional consequences of hypoglycemia, the study of FH as it relates to PTS may be a productive area of research.

Present Study

Over the past decade, there has been an increase in the research focusing on mood and anxiety symptomatology of individuals with diabetes (DM). The majority of studies

to date have focused primarily on the prevalence of anxiety and depressive psychiatric disorders among individuals with DM. One limitation of this literature is that most of these studies have combined samples of both Type I and II individuals despite these disorders being distinct etiologically. There is a paucity of studies examining mood and anxiety among individuals with insulin-dependent diabetes (IDDM), and most of these studies do not identify the method of administration for the insulin. No studies were found that compared mood and anxiety symptomatology among individuals with Type I IDDM on different intensive insulin regimens. Specifically, no studies have examined whether individuals who utilize continuous subcutaneous insulin infusion (CSII), commonly known as insulin pump therapy, relative to self-injecting methods differ in mood and anxiety symptomatology.

As previously mentioned, there are two methods of intensive insulin delivery: (a) continuous subcutaneous insulin infusion (CSII), and (b) multiple daily self-injections. Longitudinal studies have suggested that individuals with DM who utilize either of these intensive insulin therapy methods are more likely to experience severe hypoglycemia than individuals who use less intensive regimens (DCCT, 1993). This is primarily because tighter glycemic control results in a reduced margin of error before BG reaches hypoglycemic levels. However, the payoff for having tight glycemic control is the prevention of hyperglycemic states, which in turn has shown reductions in the progression of many of the long-term complications of DM (DCCT, 1993).

Individuals who experience hypoglycemia are at increased risk for developing fear of hypoglycemia (FH) reactions (Cox et al., 1987). Therefore, individuals with DM

who utilize intensive insulin regimens may experience higher levels of FH. Interestingly, one of the presumed benefits of insulin pump use is improved glycemic control, because this method mimics the natural delivery of insulin in non-diabetic individuals. However, this benefit may be placing individuals using CSII at increased risk for FH compared to individuals who self-inject. Furthermore, complications arising from hypoglycemia may be traumatic to some individuals. However, posttraumatic stress symptoms among individuals who utilize intensive insulin regimens have not been examined. Despite a number of studies examining frequency of anxiety and affective symptoms among individuals with DM, the nature of the symptomatology among these individuals, particularly individuals with Type I IDDM utilizing insulin pump therapy, has been neglected.

Even fewer studies have examined the phenomenon of fear of hypoglycemia (FH) in the IDDM population despite the increased risk of hypoglycemia for this group. Given the impact that FH has on adherence to treatment regimen and psychological well-being in individuals with DM, further study is needed. Particularly, no study has been conducted to compare fear of hypoglycemia among insulin pump users relative to those who self-inject.

Furthermore, there has been a burgeoning of interest in the relationship of posttraumatic stress (PTS) among health related and medical diagnoses. Studies have demonstrated that medical diagnoses such as cancer, spinal cord injury, myocardial infarction, and subarachnoid hemorrhage can qualify as sufficient traumatic experiences for those individuals that experience the event either personally or vicariously (i.e.,

witnessing someone else experiencing the trauma directly). However, no investigations of hypoglycemic episodes as a potential traumatic event, and any resulting PTS symptomatology have been conducted.

The primary goal of this study was to characterize further the nature of mood and anxiety symptomatology, and any relative differences among a Type I IDDM sample utilizing different intensive methods of insulin administration. This study attempted to (a) provide descriptive information regarding mood and anxiety symptoms among individuals who use both intensive insulin therapy methods, and (b) identify predictors of mood and anxiety symptoms in this population relative to which method of administration was utilized by using multiple regression methods. Specifically, multiple regression methods were used to identify whether intensive treatment regimen (i.e., multiple daily injections or insulin pump use) predicted mood and anxiety symptomatology among individuals with Type I IDDM, and whether one administration method relative to the other predicted increased mood and anxiety symptoms. The goal of this study was to uncover whether there were meaningful differences in mood and anxiety symptomatology among individuals who utilize different methods of intensive insulin administration.

CHAPTER 2: METHOD

Participants

A total of 344 participants who met the following inclusion criteria: (a) diagnosis of Type I DM, (b) have had the DM diagnosis for at least 6 months duration, (c) are age 18 years or older, and (d) use either an insulin pump or multiple daily self-injections as their method of diabetes management, were solicited for participation as described below. Of the 344 consenting participants contacted, 90 participants (26.1%) returned completed packet materials. Historically, mailed survey studies have a poor response rate. The researchers attempted to obtain as many participants as possible for the study. Participants were provided multiple self-report questionnaires regarding their diabetes and psychological well-being. All questionnaires were sent via U.S. mail. A mailing list of consenting participants was obtained from the Integrated Diabetes Services of Wynnewood, PA. The Integrated Diabetes Services (IDS) is a for-profit organization that provides individualized diabetes education and management services to children and adults. IDS specializes in intensive blood glucose management and provides insulin pump services. These services include pre-pump consultation and education, pump acquisition, technical training/pump education, and basal/bolus formula adjustments. It is from the IDS mailing list that research participants who met all inclusion criteria were selected. In order to maximize the sample size, all available participants from IDS were solicited for research participation.

Procedure

Each of the participants who met the inclusion criteria were mailed a letter from the Integrated Diabetes Services, describing the study and requesting their participation. Specifically, the letter indicated that the researchers were interested in obtaining information about mood and anxiety in individuals with DM, and that IDS agreed to assist the researchers in soliciting a sample of individuals with diabetes mellitus. The participants were informed that the study would take approximately 30 minutes to complete, and that all information would remain confidential. Additionally, the letter stated that a staff member of IDS would contact the potential participant via telephone to discuss any questions about the study, and to obtain verbal consent. The participants' verbal consent over the phone permitted the IDS staff member to supply the researchers with the names and addresses of the individuals interested in participating, so the researchers could mail out the research materials. The letter also specified that participation was completely voluntary, and the individual could decline participation without any adverse consequences.

Each potential participant was contacted via telephone by an IDS staff member, and research materials were mailed to those participants who provided verbal consent to participate. The subsequent materials that were sent via the mail included (a) a consent form explaining the purposes of the research and granting the researchers permission to obtain the participant's most recent glycosylated hemoglobin lab results (if available) from their IDS diabetes educator, (b) a demographics sheet that included general information about the individual's DM, (c) the Hypoglycemic Fear Survey-98 (HFS-98),

(d) the Beck Anxiety Inventory (BAI), (e) the modified Posttraumatic Diagnostic Scale (PTDS), which was tailored to represent a hypoglycemic episode as a potential traumatic event, (f) the Beck Depression Inventory-II (BDI-II), and (g) a self-addressed, stamped envelope for returning the survey. Each of these measures is detailed further below. All individuals were instructed that participation was completely voluntary. Each consent form and packet of questionnaires was coded for confidentiality. Participants were instructed to complete the consent form and questionnaire packet and return both in the envelope provided. All data were separated from the consent form. A separate list of the returned coded consent forms was maintained. Participants were provided with a contact telephone number, so that any questions could be answered prior to their research participation. All volunteers were mailed a written debriefing form if they wanted it, or a verbal debriefing was provided via telephone for those requesting such.

Furthermore, participants were instructed that if they agreed to complete the questionnaire packet, their name would be added to a lottery list. After all surveys were returned, one research participant was randomly selected and awarded 50 dollars. The purpose of the lottery was to act as an incentive for participation in the study.

A follow-up telephone call was made 2 weeks after the original mailing date to all individuals who had not returned research materials prompting them to participate if they so chose. The researcher attempted to contact individuals who utilize self-injection methods a second time via the telephone to encourage participation when it was discovered that more insulin pump users were participating in the study. In order to analyze whether there were any significant differences between responder and non-

responder groups, group means for various demographics were obtained via archival data provided by IDS.

Measures

Demographics Questionnaire: (see Appendix A) The demographics questionnaire is a self-report measure developed specifically for this study that asked participants to identify characteristics about themselves. Specifically, participants were instructed to provide information regarding their gender, age, ethnicity, date of DM diagnosis, general DM information including significant medical complications and/or hospitalizations, pump use/injection regimen, last glycosylated hemoglobin rate, and history of hypoglycemia episodes.

Hypoglycemic Fear Survey-98: (see Appendix B) The original Hypoglycemic Fear Survey (Cox et al., 1987) is a 27-item self-report questionnaire that contains 2 subscales. The HFS-Worry subscale consists of 17 items which measure worries about hypoglycemia. The HFS-Behavior subscale is 10 items and focuses on behaviors designed to avoid hypoglycemia. Psychometric data on the measurement indicate good internal reliability (Cox et al., 1987). For the entire scale, Cronbach's α was .90. The Behavior subscale had an α =.60, and the Worry subscale had an α =.89 (Cox et al., 1987). Test-retest reliability trials have shown temporal stability for the entire scale ranging from .68-.89, for the Behavior scale, .68-.81, and the Worry subscale, .64-.85 (Cox et al., 1987). Responses to each item of the HFS items are on a 5 point Likert scale ranging from *never* (1) to *very often* (5). Individual items are summed to produce each subscale score.

A revised version of the HFS was developed in 1998, and was provided to the present study by the authors of the instrument (D. J. Cox, personal communication, May 9, 2001). The HFS-98 contains similar items to the original form, however, six additional items are included. Five additional items have been included to the original Behavior subscale, and one additional item to the Worry subscale. Similar to the original HFS, the HFS-98 is also on a 5 point Likert scale. However, items range from *never* (0) to *always* (4). No published psychometric data are yet available on the HFS-98.

Beck Anxiety Inventory: (see Appendix C) The Beck Anxiety Inventory (BAI) is a 21-item self-report instrument that assesses the severity of anxiety in adults and adolescents (Beck, Epstein, Brown, & Steer, 1988). Each item of the BAI describes a common symptom of anxiety. Respondents are instructed to report how bothersome each symptom has been over the past week using a 4 point Likert scale ranging from *Not at all* (0) to *Severely, I could barely stand it* (3). All of the items are summed to provide a total score. Scores can range from 0 to 63.

The BAI has demonstrated good psychometric properties. In the initial psychometric study, test-retest reliability was (r= .75), and internal consistency was high (α= .92) (Beck, Epstein, Brown, & Steer, 1988). The BAI showed good convergent validity with other measures of anxiety (e.g., the Hamilton Rating Scales for Anxiety (r= .51) and the Cognition Checklist-Anxiety subscale (r= .51)). Furthermore, good discriminant validity was demonstrated with the Hamilton Rating Scales for Depression (r=.25) and the Cognition Checklist-Depression subscale (r= .22) (Beck, Epstein, Brown, & Steer, 1988).

Other studies have also supported the solid psychometric properties of the BAI. Specifically, the BAI has demonstrated high internal consistency among a sample of psychiatric outpatients (α= .92), a community sample of adults (α= .85-.92), and a non-clinical sample (α= .91) (Borden, Peterson, & Jackson, 1991; Osman, Barrios, Aukes, Osman, & Markway, 1993; Steer, Ranieri, Beck, & Clark, 1993).

Posttraumatic Diagnostic Scale: (see Appendix D) The Posttraumatic Diagnostic Scale (PTDS) is a 48-item self-report measure divided into four parts that assesses posttraumatic stress (PTS) reactions in adults (Foa, 1995). The PTDS is designed specifically to correspond with DSM-IV criteria for PTSD. Specifically, each criterion for PTSD in the DSM-IV is represented through items on the measure. This measure of PTSD was selected because it allows for differentiation of severity of PTS symptoms. For each of the DSM-IV criterion clusters, the PTDS provides both dichotomous and continuous data. Specifically, number of symptoms and symptom severity are endorsed. Part I of the measure is a 12-item checklist that requires individuals to endorse any traumatic events experienced or witnessed. Part II inquires about which traumatic event was most disturbing for the individual, time since trauma occurred, and whether physical injury to self or other occurred. Part III is a total of 18 items and corresponds to symptoms outlined in the DSM-IV PTSD criteria. Each item asks how bothered the individual has been by the specific symptom for the past month. Response to each item is on a 4 point Likert scale that ranges from *not at all or only one time* (0) to *5 or more times a week/almost always* (3). Symptom Severity Scores range from 0-51, with higher scores representing higher severity of symptomatology. Part IV consists of 9

dichotomous items listing different areas of life that might be affected by PTSD symptoms in the past month (i.e., work, home, interpersonal relationships, life satisfaction, and overall functioning). Individuals are instructed to respond either yes or no to each of the items on whether symptoms experienced have interfered with their functioning.

The PTDS shows good psychometric qualities (Foa, Cashman, Jaycox, & Perry, 1997). Internal consistency was calculated as follows: Total Symptom Severity α= .92, Reexperiencing α= .78, Avoidance α= .84, and Arousal α= .84. Test-retest reliability for the PTSD diagnosis was .74. Additionally, temporal stability was demonstrated for Total Symptom Severity (r= .83), Reexperiencing (r= .77), Avoidance (r= .81), and Arousal (r= .85). Convergent validity of the PTDS was obtained by comparing diagnosis obtained by the measure to that of the SCID. The kappa between the two measures was .65 with 82 % agreement between the two measures. Overall, the PTDS is a valid and reliable self-report instrument for both PTSD diagnoses and symptom severity (Foa et al., 1997).

For the purposes of this study, only sections III and IV (items 22-48) of the PTDS were administered. One goal of this study was to examine PTS symptomatology as it relates to the DM-related stressor, hypoglycemia. Since Parts I and II of the PTDS measure any kind of stressor experienced or witnessed by the individual, participants could endorse potentially non-DM-related events. Therefore, the rationale for omitting sections I and II was to include only those sections of the measure that could be redirected towards hypoglycemia-related aspects of PTS symptoms. Participants were instructed to respond to each of the items in the following manner. Items 22-48 were re-

written with the focus being a hypoglycemia episode as the traumatic event. For example, item 22 reads typically, *"Having upsetting thoughts or images about the traumatic event that came into your head when you didn't want them to."* This item was re-written to read *"Having upsetting thoughts or images about a low blood sugar episode that came into your head when you didn't want them to."* Items 22-28 were re-written to specify the traumatic event as "a low blood sugar episode." For the rest of the items, the participants were instructed to respond to items based on this low blood sugar episode.

In order to elucidate further to the participants that a low blood sugar episode was the stressor of interest, as well as to increase the accuracy of their self-report, modifications to the overall directions of the PTDS were made. The purpose was (a) to clarify to the participants the need to focus on a hypoglycemic episode prior to their PTS symptom endorsement, and (b) to increase the accuracy of their self-report since perceptions of past hypoglycemic episodes may be influenced by the effects of low BG. This clarification was accomplished by having the participants write a brief description of a specific hypoglycemic episode prior to completing the measure, and through repeat instruction. Namely, participants were instructed to think of a specific hypoglycemic episode that was particularly frightening. The participants were then instructed to write a brief description of that episode. While focusing only on the symptoms they experienced when they had low blood sugar, participants were instructed to respond to the questions based on that specific experience alone.

Beck Depression Inventory-II: (see Appendix E) The Beck Depression Inventory-II (BDI-II) is of the most widely used measures for the assessment of depression and is constructed to measure the severity of depression according to current diagnostic criteria in both adolescent and adult populations (Beck, Steer, Ball, & Ranieri, 1996). The BDI-II is a 21-item self-report measure. Each item is rated on a 4 point scale ranging from 0 to 3. The total score is based on the summation of the highest rating for each of the items. Total scores can range from 0 to 63. Scores ranging from 0 to 13 are categorized as 'minimal depression,' from 14 to 19 are categorized as 'mild depression,' from 20 to 28 are 'moderate depression,' and scores between 29 and 63 are categorized as 'severe depression.' The psychometric properties of the BDI-II are sound. Specifically, the BDI-II has a high internal consistency of .91, retest-reliability of .93, and convergent validity with the Hamilton Psychiatric Rating Scale for Depression (r= .71) (Beck et al., 1996). The psychometric evaluation of the BDI-II with primary care medical patients has been demonstrated (Arnau, Meagher, Norris, & Bramson, 2001), as well as with individuals with diabetes (Lustman, Clouse, Griffith, Carney, & Freedland, 1997a). In the Lustman et al. (1997a) study, depressed individuals with DM were effectively discriminated from non-depressed individuals with DM using all items of the BDI-II. However, cognitive items displayed better sensitivity than somatic items. A cutoff score of 16 or higher represents the best predictive value for mild depression in the DM population.

CHAPTER 3: RESULTS

Overview of Data Analytic Strategy

First, group means for all of the participants who met inclusion criteria were obtained via archival records provided by IDS. T-tests, for continuous data, and chi-squares, for categorical data, were then conducted to assess whether there were significant differences between the responder and non-responder groups by comparing the demographic group means of those who chose to participate in the study to those of the entire available sample. Lack of significance would suggest that the sample obtained is representative of individuals with Type I IDDM that utilize intensive insulin therapy methods. Furthermore, this would suggest that any subsequent significant findings would not be due to differences between the responder and non-responder groups, but rather be attributed to differences within the variables of interest. No further statistics were conducted on the non-responder group.

Secondly, analyses were conducted to obtain prevalence and frequency data for mood and anxiety symptomatology, and other demographic variables for the obtained sample of CSII and self-injecting individuals with DM. Thirdly, to identify predictors of mood and anxiety symptoms in the sample, simultaneous multiple regression analyses using method of insulin administration and number of self-reported hypoglycemic episodes in the last month as the predictor variables were conducted. In other methods of multiple regression, such as hierarchical and stepwise regression, the order in which the predictor variables are introduced to the analysis are manipulated by either the researcher and/or by empirical relationships between the dependent variable and other predictors.

An important consideration when using hierarchical regression is that the order in which variables are entered into the regression influences the comparability of the variables to one another at later points in the analysis, and that it artificially gives all shared variance to the first entered variable. Therefore, the researcher chooses the order of entry based on theoretical considerations. The order of variable entry for stepwise regression is based on which variable will provide the greatest increase of variance at that step. Therefore, both hierarchical and stepwise regression analyses are empirically or theoretically derived. For the present study, a less theoretically rigid regression procedure was judged to prove more useful. Therefore, the multiple regression method was conducted because the regression equation and multiple correlations are derived by simultaneously analyzing each predictor while controlling for all others in the equation.

Specific to this study, the total score for the BAI and the BDI-II, the HFS-Total score, the composite score of hypoglycemia items from the demographics questionnaire, as well as the modified version of the PTDS served as the criterion variables in the multiple regression analyses. Also, the last glycosylated hemoglobin value served as a dependent variable measuring adherence. All of the dependent variables were continuous variables. Two predictor variables were used for each of the hypotheses, method of intensive insulin administration and number of self-reported hypoglycemic episodes within the last month. The primary hypotheses of interest focused on elucidating the predictive ability of intensive insulin regimens on various measures of anxiety and depression. Therefore, one predictor variable that was used in the multiple regressions was method of intensive insulin administration (i.e., insulin pump vs. self-injection

methods). Specifically, the independent variable of method of insulin administration is identified as whether the individual utilizes CSII or multiple daily injections. Since the independent variable for method of insulin administration is dichotomous (i.e., insulin pump use or self-injecting), this independent variable was dummy coded for the analysis. A secondary hypothesis of interest was whether self-reported hypoglycemic episodes impacted depressive and anxious symptoms. Therefore, number of self-reported hypoglycemic episodes served as an additional predictor variable. Finally, a modified version of the Bonferroni procedure described below was utilized prior to interpreting the data in order to control for experiment-wise error where appropriate.

A power analysis was conducted to estimate the number of participants necessary to provide sufficient power for the regression analysis. No estimates of effect size were available in the literature, therefore a medium effect size was utilized in the power analysis. Results suggested that a minimum of 68 participants should be obtained in order to achieve a sufficient power of 80% with an alpha of .05. Therefore, the obtained sample size for this study was adequate.

Group Mean Analyses

A series of t-tests and chi-square tests were conducted to assess whether there were significant differences among the responder and non-responder groups. The t-test comparing the responder and non-responder groups on age was significant [t-test (1, 332) = 6.67, p = .001] with the responders being older than the non-responders. Given the categorical nature of the demographic variables method of administration and gender, chi-square tests were conducted to uncover any significant differences between the

responder and non-responder groups. For both the variables, method of insulin administration and gender, significant statistical differences were also yielded [χ^2 = 29.29, p = .001; χ^2 = 9.711, p = .002]. Specifically, a higher of number insulin pump users than insulin shot users were represented in the responder group compared to the non-responder group. Additionally, the responder group contained a significantly higher number of females compared to the non-responder group. For chi-square analyses, unequal cell sizes are permissible as long as the expected frequency in each cell is at least 5 (Howell, 1992). For both chi-square analyses conducted, none of the frequency cells yielded a sample size of less than five. These results suggest that interpretations of the hypothesized results from the regression analyses for the predictor variable, method of intensive insulin administration, should be made with caution. Notably, for the responding group, 77 of the 90 participants (85.5 %) utilize insulin pumps, whereas only 13 individuals (14.4 %) utilize insulin shots. However, among the non-responding group, 116 of 220 individuals (52.7 %) utilize insulin pumps, 104 of 220 individuals (47.2 %) utilize insulin shots, and 24 individuals (10.9 %) did not have a current method of insulin administration classified in the archival database. Overall, this suggests that the original available database from which potential research participants were solicited was approximately equal with regards to number of insulin pump users and self-injectors. However, it remains unclear why a statistically larger number of insulin pump users completed the study compared to those who self-inject. Additionally, the chi-square for gender was significant. Interestingly, in the responder group, 65 participants (72 %) were female and 25 participants (28 %) were male. In the non-responder group, 130

individuals (53.3 %) were female and 114 individuals (46.7 %) were male. Once again, this suggests that the original database from which potential participants were solicited was approximately equal in number of males and females. Additionally, the average age for the non-responder group was 37.4 years of age, whereas the average age for those that participated in the study was 43.2 years. This indicates that the responding and non-responding groups were close in approximate age, nonetheless the difference was statistically significant.

Comparisons of the Methods of Insulin Administration

As previously mentioned, the majority of studies to date have focused primarily on the prevalence of mood and anxiety disorders among individuals with diabetes. However, limitations of these studies include combined samples of both Type I and II individuals, as well as no differentiation among the method of insulin administration used. Additionally, no studies were found that compared insulin pump users and self-injectors on a variety of demographic and descriptive variables. Therefore, a series of t-tests and chi-squares were conducted to compare patients who utilized CSII relative to those who self-inject on mood and anxiety symptoms as well as various demographic variables (see Table 1). The goal of these analyses was to further elucidate the qualitative and descriptive differences among the two methods of administration. A series of t-tests and chi-squares were conducted as the means for uncovering demographic differences among the methods of administration. As noted above, there was a difference in sample size obtained for participants who use insulin shots versus those who use an insulin pump. Despite the difference in sample sizes, t-tests were

performed on the continuous data. Specifically, given a sufficient sample size, the t-test remains fairly robust to moderate departures of the underlying assumptions (Howell, 1992). Additionally, the t-test is robust with regards to non-normality of sample distribution particularly if the standard deviations between independent samples are approximate to one another (Tabachnick & Fidell, 1996). For this sample, the relative standard deviations for all of the separate t-tests were not sufficiently discrepant from one another. Additionally, since there was a minimum of 13 individuals in each condition, the t-test is a reasonable analysis. This is particularly salient given that the purpose of the t-tests is to further ascertain demographic and frequency data between the two methods of administration.

The Bonferroni correction is a highly conservative correction for experiment-wise error when multiple t-tests and chi-squares are conducted. All procedures that control Type I error impact Type II error as well. The Bonferroni correction protects against Type I error so much that Type II error becomes overly inflated to unacceptable levels particularly for use in an exploratory study. Therefore, a method for protecting against experiment-wise error without inflating Type II error too much was used. Therefore, a modified version of the Bonferroni correction was utilized in this study to control for experiment-wise error from the multiple t-tests and chi-squares. Specifically, dependent variables were theoretically clustered together and then the Bonferroni correction was applied to the significance levels for each specific cluster.

Seven conceptual clusters of the dependent variables were established, and Bonferroni corrections were calculated for each cluster. The first conceptual cluster

consisted of general identifying demographics of the sample (i.e., age, age when first diagnosed with diabetes, gender, and race/ethnicity). The modified Bonferroni correction established that an alpha level less than .0125 was required for statistical significance. 1) Current age was not significantly different among the two method of insulin administration groups [*t*-test (1, 88) = 1.933, $p = .056$]. The average current age for the entire sample of participants was 43.2 years. The average current age for those individuals who utilize self-injections was 36.5 years, whereas it was 44.4 years for those participants who use an insulin pump. 2) Age when first diagnosed with diabetes was not significantly different [*t*-test (1, 87) = -.039, $p = .969$]. The average age of diabetes onset for insulin pumps users was 19.87 years, whereas it was 20 years for those individuals who self-inject insulin. The two variables of gender and race/ethnicity are categorical variables. Chi-squares were conducted to assess for statistical significance. The two administration groups did not statistically differ with regards to gender [$\chi^2 = .167$, $p = .682$]. However, the ratio of women-to-men participating in the study was statistically significant [$\chi^2 = 17.78$, $p = .001$]. For the entire sample a total of 65 females (72.2 %) and 25 males (27.8 %) chose to participate in the study. Among the self-injection group, ten participants (76.9 %) were female, and three were male (23.1 %). Among those participants who utilize an insulin pump, 55 (71.4 %) were female, and 22 (28.6 %) were male. This suggests that men are slightly more likely to use an insulin pump than insulin shots. Women are slightly more likely to use insulin shots than CSII methods. The two methods of administration did not statistically differ with regards to race/ethnicity [$\chi^2 = .792$, $p = .374$]. However, Caucasians were more likely to participate in the study than

other ethnicities [$\chi^2 = 285.11$, $p = .001$]. Caucasians were relatively equal with regards to percentage who use insulin pumps compared to shots. Although not significant, African-Americans were slightly more likely to use insulin pumps than insulin shots. For the total sample, 82 participants (91.1 %) classified themselves as 'Caucasian' and five participants (5.6 %) classified themselves as 'African-American". One individual (1.1 %) was classified as 'Hispanic', one participant (1.1 %) as 'Native American', and another as 'Other' which was further classified as 'Asian'. Among the self-injecting group, 11 individuals (84.6 %) classified themselves as 'Caucasian'. One participant (7.7 %) endorsed 'Hispanic' and another individual (7.7 %) endorsed 'Native American' as their ethnicity groups. Among the insulin pump group, 71 individuals (92.2 %) reported that they are 'Caucasian', five (6.5 %) participants classified themselves as 'African-American', and one individual (1.3 %) endorsed 'Other-Asian'.

The second conceptual cluster consisted of variables associated with cognitive awareness of hypoglycemia (i.e., ever experiencing low blood sugar, lowest BG ever reported, and fear of death). The alpha level required to reach statistical significant was $p = .016$. 1) The number of individuals reporting *ever* having a low blood glucose reading was not significantly different among the two intensive regimens [$\chi^2 = .345$, $p = .557$]. A total of 88 participants (97.8 %) reported a history of at least one hypoglycemic episode. All of the individuals in the self-injecting group reported having had a low blood glucose episode. Ninety-seven percent of the insulin pump group (75 individuals) reported having recorded at least one low blood sugar episode. 2) The two administration groups displayed no significant differences with regards to lowest blood

glucose (BG) ever recorded [*t*-test (1, 87) = -.720, p = .473]. The average of the lowest BG recordings for the self-injecting group was 29 mg/dl. The lowest recording for this group was 15 mg/dl. For the insulin pump group, the average of the lowest BG recordings was 27 mg/dl. The lowest recording for this group was 6 mg/dl. 3) The number of participants who reported ever fearing death would occur as a result of a hypoglycemic episode was not statistically significant among the method of administration groups [χ^2 = 1.88, p = .169]. A total of 27 participants (30 %) reported fearing death due to hypoglycemia. Six participants (46.2 %) of the self-injecting group endorsed fear of death resulting from hypoglycemia. Among participants who utilize insulin pumps, 21 individuals (27.3 %) reported fear that death would occur due to a low blood sugar episode.

The third conceptual cluster consisted of dependent variables related to possible consequences of a sudden drop in blood sugar. The dependent variables of interest were automobile accidents secondary to hypoglycemia, employment reprimands or terminations, and requiring assistance from others. The modified Bonferroni correction established an alpha of .016 as statistically significant. 1) Participants reporting having an automobile accident resulting from hypoglycemia was not statistically significant between the two administration groups [χ^2 = .180, p = .672]. A total of 10 participants (11.1 %) reported having a low blood sugar episode that resulted in an automobile accident. Among the participants who utilize self-injection methods, only one individual (7.7 %) disclosed a hypoglycemia related car accident. Nine participants (11.7 %) who utilize insulin pumps reported an automobile accident due to low blood sugar. 2) The

number of individuals reporting a formal employment reprimand or job termination due to hypoglycemia-related behaviors did not significantly differ among the two method of administration groups [$\chi^2 = 2.09$, $p = .148$]. A total of two individuals (2.2 %) endorsed having been formally reprimanded or fired from a job due to hypoglycemia-related behaviors (i.e., cognitive dulling, disorientation). One individual (7.7 %) who utilizes self-injection methods and one individual (1.3%) who utilizes an insulin pump reported a formal reprimand or termination from employment for hypoglycemic behaviors. 3) The two method of administration groups did not statistically differ in ever having a hypoglycemic episode that required assistance from others [$\chi^2 = .122$, $p = .727$]. A total of 73 participants (81.1 %) of the total sample reported requiring assistance from another person due to a low blood sugar episode. A total of 11 individuals (84.6 %) who utilize self-injecting methods endorsed a hypoglycemic episode that required assistance from a second party. Among the insulin pumps users, 62 participants (80.5 %) indicated that they have experienced a low blood sugar episode that required outside assistance from another.

The fourth conceptual cluster consisted of variables that identified sudden medical consequences secondary to hypoglycemia. The dependent variables in this cluster include: hypoglycemic seizure, loss of consciousness, requiring assistance from paramedics, trips to the emergency room, and number of hypoglycemia-related hospitalizations. The modified Bonferroni correction yielded an alpha of .01 for statistical significance. 1) The number of individuals endorsing an episode of a low BG seizure did not statistically differ among the two method of administration groups [$\chi^2 =$

.049, p = .825]. A total of 23 individuals (25.6 %) reported having a hypoglycemia induced seizure. Three participants (23.1 %) who utilize self-injection methods indicated experiencing a low BG seizure, whereas 20 individuals (26 %) who utilize CSII methods reported hypoglycemia induced seizures. 2) The two method of insulin administration groups did not significantly differ in experiencing a loss of consciousness (LOC) due to low blood sugar [χ^2 = .308, p = .579]. A total of 41 participants (45.6 %) reported passing out or losing consciousness due to hypoglycemia. Among the self-injecting group, five participants (38.5 %), endorsed hypoglycemia induced LOC. A total of 36 insulin pump users (46.8 %) reported a history of losing consciousness due to low blood sugar. 3) Insulin pumps users and individuals who utilize self-injecting methods did not significantly differ in experiencing a hypoglycemic episode that resulted in requiring paramedic assistance [χ^2 =.002, p = .968]. A total of 42 participants in the study, (46.7 %), reported experiencing a hypoglycemic episode that required assistance from paramedics. A total of six individuals (46.2 %) who utilize self-injecting insulin methods reported needing emergency medical services. Similar prevalence rates were found for insulin pump users. A total of 36 individuals utilizing CSII methods, (46.8 %) indicated having a hypoglycemic episode that resulted in paramedic assistance. 4) Insulin pumps users and individuals who self-inject did not significantly differ in having a hypoglycemia-related trip to the local emergency room [χ^2 = 3.53, p = .06]. A total of 35 participants (38.9 %) reported presenting to an emergency room due to hypoglycemia. Among the self-injecting group, two participants (15.4 %) indicated having a low BG episode that sent them to the ER. A total of 33 individuals (42.9 %) who utilize insulin

pumps reported that a low blood sugar episode has resulted in a trip to the emergency department. This suggests that insulin pump users do not report the experience of a hypoglycemia-related trip to the ER more than their self-injecting counterparts. 5) The two methods of administration did not statistically differ in the number of hypoglycemic hospitalizations reported [*t*-test (1, 88) = -1.358, $p = .178$]. The average number of low BG hospitalizations reported by the entire sample was 0.6. Specifically, 81.1 % of the sample reported no hypoglycemic hospitalizations. The highest number of reported hospitalizations was 15. A total of 11 individuals (84.6 %) who use self-injecting techniques reported no hospitalizations secondary to hypoglycemia. However, one of these individuals reported a history of two low BG hospitalizations, and another participant reported a history of 15 hospitalizations. Among the insulin pump group, the average number of low BG hospitalizations was 4.8. Among this group, 80.5 % reported no hypoglycemic hospitalizations. The highest number of low BG hospitalizations reported for this group was 10.

The fifth conceptual cluster identified vision problems secondary to diabetes. Two dependent variables were used, and a modified Bonferroni correction yielded $p = .025$ as the critical significance level. 1) Complications from diabetes resulting in blindness was not significantly different among the two groups [$\chi^2 = 2.09$, $p = .148$]. A total of two individuals (2.2 %) reported having complete vision loss secondary to problems from diabetes. One of these individuals (7.7 %) self-injects insulin, and the other individual (1.3 %) uses an insulin pump. 2) Complications from diabetes resulting in vision changes and/or retina complications, but not blindness, was not significantly

different among the two groups [$\chi^2 = 2.28$, $p = .131$]. A total of 38 individuals (42.2 %) reported having vision problems related to their diabetes. Three individuals (23.1 %) self-inject insulin, and 35 individuals (45.5 %) use an insulin pump.

The sixth conceptual cluster represented complications often comorbid with uncontrolled diabetes. Specifically, the dependent variables representing the cluster included: kidney and heart problems, "other" complications, and a diabetes-related hospitalization. The modified Bonferroni correction yielded an alpha value of .0125 for statistical significance. 1) Complications from diabetes resulting in end-stage renal disease (ESRD) or kidney disease was not significantly different among the two groups [$\chi^2 = 0.00$, $p = .990$]. A total of seven individuals (7.8 %) endorsed having ESRD or kidney disease related to diabetes complications. Only one individual (7.7 %) uses the self-injection method, whereas six individuals (7.8 %) were from the insulin pump group. 2) Cardiac complications from diabetes resulting in either myocardial infarction (MI) or heart problems was not significantly different among the two groups [$\chi^2 = 0.00$, $p = .990$]. A total of seven individuals (7.8 %) reported having diabetes-related cardiac problems. One individual (7.7 %) self-injects insulin, and six individuals (7.8 %) use an insulin pump. 3) Participants were allowed to endorse "other" as a choice for complications experienced secondary to diabetes. The results yielded no significant differences among the two groups [$\chi^2 = .411$, $p = .521$]. A total of 20 individuals (22.2 %) reported having complications related to their diabetes. Two individuals (15.4 %) utilize self-injection methods, and 18 individuals (23.4 %) use an insulin pump. A few of the complications that were endorsed included: impotence, carpal tunnel syndrome,

hypertension (HTN), periodontal disease, gastroparesis, gestation retinopathy, microalbuminuria, and TBI secondary to hypoglycemic coma. 4) Being hospitalized due to diabetes-related complications was not statistically significant among the two groups [$\chi^2 = 1.439$, $p = .230$]. A total of 18 individuals (20 %) reported having been hospitalized for diabetes complications. Only one individual (7.7 %) from the self-injecting group endorsed requiring hospitalization, whereas 17 individuals (22.1 %) who use insulin pumps reported prior hospitalizations.

The final conceptual cluster represented neuropathy-related (circulatory) problems. The dependent variables of interest were experiencing an amputation, stroke, and neuropathy complications. The modified Bonferroni correction yielded $p = .016$ as the significance level. 1) The experience of having a diabetes-related amputation among the two groups was not significantly different [$\chi^2 = .896$, $p = .344$]. A total of three individuals (3.3 %) indicated having an amputation secondary to problems from diabetes. One individual (7.7 %) self-injects insulin, whereas two individuals (2.6 %) use the CSII method. 2) Individuals reporting complications of a diabetes-related stroke was not significantly different among the two groups [$\chi^2 = 2.798$, $p = .094$]. A total of five individuals (5.6 %) reported having a stroke secondary to their diabetes. Two individuals (15.4 %) utilize self-injection methods, and three individuals (3.9 %) use an insulin pump. 3) Complications from diabetes resulting in neuropathy was marginally significantly different among the two groups [$\chi^2 = 5.525$, $p = .019$] after applying the modified Bonferroni correction to control for experiment-wise error. A total of 24 individuals (26.7 %) indicated having circulatory problems secondary to diabetes.

Interestingly, none of the individuals who utilize self-injection methods reported neuropathy complications. Whereas, 24 individuals (31.2 %) who utilize an insulin pump indicated circulation problems. Therefore, in this sample, individuals who utilize CSII methods were more likely to report problems of neuropathy than their self-injecting counterparts.

Two additional frequency descriptives were calculated for each of the administration groups. 1) Among the self-injection group, the average number of daily insulin injections was 4.3. Three individuals (23.1 %) reported three insulin injections daily. Five individuals (38.5 %) reported four insulin shots daily. Three participants (23.1 %) reported five daily injections of insulin, and two individuals reported six insulin injections daily. 2) Insulin pump users were instructed to endorse the length of time that they have been using CSII methods. The length of time using an insulin pump ranged from 5 to 267 months. The average length of time for insulin pump use was 51.5 months.

All of the items in clusters 2 through 7 with the exception of *"fear of death from hypoglycemia"* were compiled into a global total severity score of low BG experiences. Median split values were calculated for the continuous dependent variables (i.e., number of hospitalizations, lowest BG recorded, etc.) to create categorical data. All items were summed together to create a global total severity score which represented an overall score of complications from low BG. A multiple regression was conducted to examine the predictive ability of method of administration and number of low BG experiences on total low BG severity, and yielded non-significant results [$r^2 = .034$; $b_{(Method\ of\ Administration)} = -1.201$, $SE = .844$, $p = .178$; $b_{(Monthly\ Low\ BG)} = -.856$, $SE = .687$, $p = .216$].

Hypothesized Results and Findings

(See Table 2)

All of the planned and exploratory analyses were tested for nonlinearity and interaction effects. Specifically, the effects of method of administration, number of hypoglycemic episodes, age, and gender on each criterion variable were linear. No significant interactions were found.

Hypothesis 1(a): *Method of intensive insulin administration will predict level of FH (Fear of Hypoglycemia). Specifically, individuals who utilize insulin pumps will report significantly higher levels of FH, as measured by the HFS-98 and the composite score of the demographics questionnaire, compared to individuals who self-inject.*

Hypothesis 1(b): *The number of self-reported hypoglycemic episodes will predict FH (Fear of Hypoglycemia). Specifically, individuals who report more frequent hypoglycemic episodes will report elevated levels of FH, as measured by the HFS-98 and the composite score of the demographics questionnaire.*

Hypotheses (1a) and (1b) were evaluated by means of a multiple regression analysis. For hypothesis (1a), the predictor variable of interest was method of insulin administration, whereas for hypothesis (1b) the predictor variable of interest was number of self-reported hypoglycemic episodes. The HFS-98 total score and composite score of the demographics questionnaire served as the criterion variables for these hypotheses. The composite fear score was the combined total of eleven questions on the demographics questionnaire that assessed for level of fear towards hypoglycemia and diabetes-related complications. Two multiple regressions were conducted to determine

the contributions that method of insulin administration and number of hypoglycemic episodes have on fear of hypoglycemia (FH). The multiple regression using the HFS-total score as the criterion variable was non-significant [adjusted $r^2 = .009$; $b_{(Method\ of\ Administration)} = 9.638$, $SE = 5.924$, $p = .107$; $b_{(Monthly\ Low\ BG)} = .141$, $SE = .248$, $p = .572$]. However, the relationship between method of administration and the HFS-98 total score was marginally significantly correlated as represented by the Pearson correlation ($r = .167$, $p = .059$). This suggests that insulin shot users have slightly higher HFS-98 total scores. Specifically, when controlling for number of self-reported hypoglycemic episodes, the mean HFS-total score for individuals who utilize the self-injection method of administration ($M = 47.15$, $SD = 26.99$) was approximately 9.63 points higher than those individuals who utilize insulin pumps as their method of administration ($M = 37.82$, $SD = 17.95$). Nevertheless, the higher scores on the HFS-total for self-injectors were not significant.

The demographics fear composite score yielded similar non-significant results as the HFS-98 total score when it was the criterion variable for the second multiple regression [adjusted $r^2 = -.017$; $b_{(Method\ of\ Administration)} = 2.701$, $SE = 4.196$, $p = .522$; $b_{(Monthly\ Low\ BG)} = .08$, $SE = .176$, $p = .648$]. When controlling for number of self-reported hypoglycemic episodes, the mean composite fear score for individuals who utilize the self-injection method of administration ($M = 46.62$, $SD = 16.34$) was approximately 2.7 points higher than those individuals who utilize insulin pumps as their method of administration ($M = 43.79$, $SD = 13.62$). However, the higher scores on the composite fear score for self-injectors were not significant.

The HFS-98 is comprised of two subscales, the Worry and Behavior subscales. Two additional exploratory multiple regression analyses were conducted to elucidate whether administration technique is related to fear of hypoglycemia as represented by behavioral fear (Behavior subscale) and cognitive fear (Worry subscale) rather than a collective total fear score (HFS-total score). For the two multiple regression analyses, the predictor variables were once again method of insulin administration and number of self-reported hypoglycemic episodes. The Worry and Behavior subscales served as the criterion variables, respectively, for each of the analyses.

Results for the multiple regression using the HFS-Worry score as the criterion variable were consistent with the non-significant findings of the HFS-total score [adjusted $r^2 = .009$; $b_{(Method\ of\ Administration)} = 5.514$, $SE = 4.042$, $p = .176$; $b_{(Monthly\ Low\ BG)} = .188$, $SE = .169$, $p = .269$]. When controlling for number of self-reported hypoglycemic episodes, the mean HFS-Worry score for individuals who utilize the self-injection method of administration ($M = 27.23$, $SD = 17.33$) was approximately 5.51 points higher than those individuals who utilize insulin pumps as their method of administration ($M = 22.17$, $SD = 12.58$). However, the higher scores on the HFS-Worry for self-injectors were not significant.

The regression analysis for the Behavior subscale of the HFS-98 yielded slightly different results. The overall multiple regression was not significant [adjusted $r^2 = .015$; $b_{(Method\ of\ Administration)} = 4.124$, $SE = 2.424$, $p = .092$; $b_{(Monthly\ Low\ BG)} = -.047$, $SE = .101$, $p = .640$]. However, the method of insulin administration and the HFS-98 Behavior subscale were significantly correlated ($r = .187$, $p = .04$). This suggests that self-injecting

participants score higher than insulin pump users on the behavior subscale of the HFS. The mean HFS-Behavior score for individuals who utilize the self-injection method of administration (M = 19.92, SD = 11.13), when controlling for number of self-reported hypoglycemic episodes, was approximately 4.12 points higher than those individuals who utilize insulin pumps as their method of administration (M = 15.65, SD = 7.31). However, the higher scores on the HFS-Behavior scale for those individuals who use self-injecting methods were not significant.

Hypothesis 2(a): *Method of intensive insulin administration will predict glycemic control. Specifically, individuals who utilize insulin pumps will have better adherence compared to individuals who self-inject, relative to normal healthy ranges, as measured by lower glycosylated hemoglobin values.*

Hypothesis 2(b): *The number of self-reported hypoglycemic episodes will predict glycemic control. Specifically, individuals who report more frequent hypoglycemic episodes will have poorer adherence relative to normal ranges, as measured by lower glycosylated hemoglobin values.*

Hypotheses (2a) and (2b) were evaluated by means of a multiple regression analysis. For hypothesis (2a), the predictor variable of interest was method of insulin administration, whereas for hypothesis (2b) the predictor variable of interest was number of self-reported hypoglycemic episodes. The last recorded glycosylated hemoglobin level (A1c) served as the criterion variable for these hypotheses. One multiple regression was conducted to determine the contributions that method of insulin administration and number of hypoglycemic episodes have on overall glycemic control.

The overall multiple regression was statistically non-significant [adjusted r^2 = .031; $b_{(Method\ of\ Administration)}$ = .903, *SE*= .419, *p* = .034; $b_{(Monthly\ Low\ BG)}$ = -.003, *SE*= .017, *p* = .857]. One zero-order correlation was significant. Specifically, the relationship between method of administration and last A1c level was significantly correlated as represented by the Pearson correlation (*r* = .231, *p* = .015) and a separate t-test for this beta unstandardized coefficient was statistically significant [b = .903, *t*-test (2, 87) = 2.155, *p* =.034]. This indicates that the last recorded A1c level for individuals who utilize the self-injection method of administration (*M* = 7.99, *SD* =2.31), when controlling for number of self-reported hypoglycemic episodes, was statistically .903 points higher than those individuals who utilize insulin pumps as their method of administration (*M* = 7.07, *SD* = 1.11). This suggests that individuals who utilize self-injection techniques report higher Alc levels than their CSII counterparts. This regression equation yielded an unstandardized coefficient for number of low blood sugar episodes equivalent to -.03. This suggests that for every additional low blood sugar episode that is reported, there is a .03 decrease in the overall glycosylated hemoglobin level. Although not a significant decrease, this makes intuitive sense. Specifically, the glycosylated hemoglobin level is a measure of glycemic control (i.e., a 2-3 month estimate of the individual's ability to control for hyperglycemia). Those individuals that have more reported hypoglycemic episodes may have lower overall A1c, because they are having more frequent periods of low blood sugar episodes than high blood sugar episodes.

Hypothesis 3(a): *Method of intensive insulin administration will predict level of FH-related PTDS. Specifically, individuals who utilize insulin pumps will report*

significantly higher levels of FH-related posttraumatic stress, as measured by the modified version of the PTDS, compared to individuals who self-inject.

Hypothesis 3(b): *The number of self-reported hypoglycemic episodes will predict level of FH-related PTDS. Specifically, individuals who report more frequent hypoglycemic episodes will report significantly higher levels of FH-related posttraumatic stress, as measured by the modified version of the PTDS.*

Hypotheses (3a) and (3b) were evaluated by means of a multiple regression analysis. For hypothesis (3a), the predictor variable was method of insulin administration, whereas for hypothesis (3b) the predictor variable was number of self-reported hypoglycemic episodes. The modified version of the PTDS total severity score served as the criterion variable for these hypotheses. The multiple regression was conducted to determine the contributions that method of insulin administration and number of hypoglycemic episodes have on hypoglycemic posttraumatic stress.

The overall multiple regression was non-significant [adjusted $r^2 = -.004$; $b_{(Method\ of\ Administration)} = 3.396$, $SE = 2.813$, $p = .231$; $b_{(Monthly\ Low\ BG)} = .07$, $SE = .118$, $p = .550$]. When controlling for number of self-reported hypoglycemic episodes, the PTDS severity score for individuals who utilize the self-injection method of administration ($M = 12.69$, $SD = 9.81$) was 3.396 points higher than those individuals who utilize insulin pumps as their method of administration ($M = 9.44$, $SD = 9.14$). The higher total severity score on the PTDS for people who utilize self-injection methods was not significantly higher than for those who utilize insulin pumps.

The total severity score on the PTDS is a continuous variable, and therefore was treated as the primary criterion variable for these hypotheses. However, the PTDS can also be scored to provide information on whether the individual met full diagnostic criteria for posttraumatic stress disorder as categorized by the DSM-IV. An exploratory multiple regression analysis was conducted using the PTDS diagnostic score (a binary score of meeting criteria or not meeting criteria) as the criterion variable. The predictor variables were method of insulin administration and number of self-reported low blood sugar episodes. A dichotomous dependent variable is permitted within regression analysis. However, with the dummy coding that is required for the criterion variable, the unstandardized coefficient (*b)* and overall *Y* must be interpreted as proportions (Cohen and Cohen, 1983). A total of 23 participants (25.5%) met criteria for posttraumatic stress disorder based on the modified version of the PTDS. Five individuals who utilize the self-injection method (38.4% of this specific sample) and 18 individuals who utilize insulin pumps (23.3% of this specific sample) met criteria for posttraumatic stress disorder as measured by the PTDS diagnostic score. The overall multiple regression was statistically non-significant [adjusted r^2 = -.008; $b_{(Method\ of\ Administration)}$ = .143, *SE*= .133, p = .287; $b_{(Monthly\ Low\ BG)}$ = -.001, *SE*= .006, p = .755]. This suggests that the probability of meeting current PTSD criteria, when controlling for number of self-reported hypoglycemic episodes, was slightly higher for those who utilize the self-injection method of administration than those individuals who utilize insulin pumps as their method of administration. However, this slight increase in probability was not statistically significant.

Additional prevalence data were collected to elucidate the percentage of responding for each of the symptom clusters within the PTDS (See Table 3). As previously mentioned, the PTDS total severity score is comprised of three symptom clusters: re-experiencing, avoidance, and arousal. Each symptom cluster was examined and individuals "met criteria" based on the number of items within each cluster that were endorsed. Each cluster's criteria were founded on the DSM-IV criteria for PTSD. Namely, to meet criteria for "re-experiencing" an individual had to endorse one or more items in that specific cluster, three or more in the "avoidance" cluster, and two or more in the "arousal" cluster. All chi-squares were non-significant suggesting that there were no statistical differences among the self-injectors and pump users on each of the three symptom clusters, re-experiencing, avoidance, and arousal [$\chi^2 = .091$, $p = .763$, $\chi^2 = .678$, $p = .410$, $\chi^2 = 1.339$, $p = .247$, respectively]. Within the total sample, 65.5 % met criteria on the re-experiencing cluster, 31.1 % met criteria for avoidance symptoms, and 54.4 % met criteria for the arousal cluster. Additionally, 69.2 % of self-injectors and 64.9 % of insulin pump users met criteria for re-experiencing symptoms. Among the self-injectors, 38.4 % endorsed avoidance symptoms compared to 29.8 % of insulin pump users. Finally, 69.2 % of the self-injectors compared to 51.9 % of the insulin-pump users endorsed arousal symptoms.

Hypothesis 4(a): *Method of intensive insulin administration will predict level of depression. Specifically, individuals who utilize insulin pumps will report significantly higher levels of depression, as measured by the BDI-II, compared to individuals who self-inject.*

Hypothesis 4(b): *The number of self-reported hypoglycemic episodes will predict level of depression. Specifically, individuals who report more frequent hypoglycemic episodes will report elevated levels of depression, as measured by BDI-II.*

Hypotheses (4a) and (4b) were evaluated by means of a multiple regression analysis. The predictor variables were method of insulin administration and number of self-reported hypoglycemic episodes. Total score on the BDI-II served as the criterion variable. The overall regression analysis was not statistically significant [adjusted r^2 = -.023; $b_{(Method\ of\ Administration)}$ = -.501, *SE*= 2.952, *p* = .866; $b_{(Monthly\ Low\ BG)}$ = .003, *SE*= .124, *p* = .978]. When controlling for number of self-reported hypoglycemic episodes, the BDI-II score for individuals who utilize the self-injection method of administration (*M* = 11.38, *SD* =7.73) was .501 points lower than those individuals who utilize insulin pumps as their method of administration (*M* = 11.74, *SD* =10.02). The higher recorded BDI-II score for people who utilize insulin pumps was not significant.

Hypothesis 5(a): *Method of intensive insulin administration will predict level of anxiety. Specifically, individuals who utilize insulin pumps will report significantly higher levels of anxiety, as measured by the BAI, compared to individuals who self-inject.*

Hypothesis 5(b): *The number of self-reported hypoglycemic episodes will predict level of anxiety. Specifically, individuals who report more frequent hypoglycemic episodes will report elevated levels of anxiety, as measured by BAI.*

Hypotheses (5a) and (5b) were evaluated by means of a multiple regression analysis. The predictor variables were method of insulin administration and number of self-reported hypoglycemic episodes. The criterion variable was total score on the BAI.

The overall multiple regression was non-significant [adjusted $r^2 = .021$; $b_{(Method\ of\ Administration)} = 5.367$, $SE = 2.713$, $p = .051$; $b_{(Monthly\ Low\ BG)} = .001$, $SE = .114$, $p = .920$]. The zero-order correlations yielded one significant relationship. The relationship between method of insulin administration and the BAI was significantly correlated ($r = .209$, $p = .025$). This suggests that participants who use CSII methods reported lower levels of anxiety than their self-injecting counterparts. The BAI total score for individuals who utilize the self-injection method of administration ($M = 15.232$, $SD = 10.66$), when controlling for number of self-reported hypoglycemic episodes, was approximately 5.367 points higher than those individuals who utilize insulin pumps as their method of administration ($M = 9.793$, $SD = 8.61$). The higher recorded BAI score for people who utilize self-injection methods was significantly higher than for those who utilize insulin pumps.

Additional Exploratory Regression Analyses

(See Table 4)

Additional exploratory multiple regression analyses were conducted to ascertain the predictive ability that age and gender may have on all of the criterion variables of interest. Specifically, a series of multiple regression analyses with the predictor variables, gender and age, were conducted. The criterion variables that were used were the HFS-total, composite fear score on the demographics questionnaire, HFS-Worry, HFS-Behavior, last reported glycosylated hemoglobin (A1c), PTDS severity score, the diagnostic score for the PTDS, BDI-II, and BAI-II.

Four exploratory multiple regression analyses were conducted to investigate the predictive influence of age and gender on fear of hypoglycemia (FH). For the first multiple regression, the criterion variable was the HFS-total. The overall multiple regression was not statistically significant [adjusted r^2 = .019; $b_{(Gender)}$ = -8.75, *SE* = 4.832, *p* = .074; $b_{(Age)}$ = -.006, *SE*= .158, *p* = .967]. One of the zero order correlations was significant. Specifically, the relationship between gender and the HFS-98 total score was significantly negatively correlated (*r* = -.203, *p* = .028). This indicates that, when controlling for age, the mean HFS-total score for men (*M* = 32.8, *SD* = 16.13) was approximately 8.75 points lower than it was for women (*M* = 41.62, *SD* =20.37). Although the correlation between gender and the HFS-total score was significant, a t-test for the significance of the gender controlling for age was non-significant [*t*-test (1, 89) = -1.811, *p* = .074]. Therefore, the scores on the HFS-total for woman are not significant higher than for men. This suggests that women report higher HFS-98 total scores than men. Additionally, the relationship between gender and current age without regards for the HFS-total score was statistically significant (*r* = .325, *p* = .001).

The second exploratory multiple regression examining the predictive influence of age and gender on fear of hypoglycemia used the composite fear score on the demographics questionnaire as the criterion variable. The demographics fear composite score yielded similar results when it was the criterion variable for the multiple regression [adjusted r^2 = .022; $b_{(Gender)}$ = -5.434, *SE* = 3.441, *p* = .118; $b_{(Age)}$ = -.07, *SE*= .113, *p* = .525]. The relationship between gender and the demographics fear composite score was significantly negatively correlated (*r* = -.198, *p* = .031), which indicates that women

report higher overall fear total scores than men. When controlling for age, the mean composite fear score for female participants (M = 45.91, SD =13.46) was approximately 5.34 points higher than for their male counterparts (M = 39.76, SD = 14.61). However, despite the significant correlation between gender and the composite fear scores, the higher scores for females was not significantly different than the male's scores when controlling for the influence of age [t-test (1, 89) = -1.579, p = .118].

As previously mentioned, the HFS-98 is comprised of two subscales, the Worry and Behavior subscales. Two additional exploratory multiple regression analyses were conducted to ascertain whether gender and current age is related to fear of hypoglycemia as represented by behavioral fear (Behavior subscale) and cognitive fear (Worry subscale) rather than a collective total fear score (HFS-total score). The Worry and Behavior subscales served as the criterion variables, respectively, for each of the analyses.

Results for the multiple regression using the HFS-Worry score as the criterion variable were consistent with the findings of the HFS-total score [adjusted r^2 = .028; $b_{(Gender)}$ = -5.962, SE = 3.282, p = .073; $b_{(Age)}$ = -.04, SE= .107, p = .647]. One of the zero-order correlations was significant. Specifically, the relationship between gender and the HFS-Worry score was significantly negatively correlated (r = -.217, p = .02). This suggests that women report higher cognitive worry of FH than their male counterparts. Specifically, when controlling for age, the mean HFS-Worry score for female participants (M = 24.69, SD = 14.04) was approximately 5.96 points higher than for the male participants (M = 18.24, SD = 10.31). However, the difference between the genders on

this measure was not significant when controlling for age [*t*-test (1,89) = -1.817, *p* = .073].

The regression analysis for the Behavior subscale of the HFS-98 yielded slightly different results [adjusted r^2 = .000; $b_{(Gender)}$ = -2.788, *SE* = 2.00, *p* = .167; $b_{(Age)}$ = .04, *SE*= .065, *p* = .516]. Specifically, the relationship between gender and the HFS-98 Behavior subscale was not significantly correlated (*r* = -.132, *p* = .107). The mean HFS-Behavior score for men (*M* = 14.56, *SD* = 7.55), when controlling for age, was approximately 2.78 points lower than for their female counterparts (*M* = 16.92, *SD* = *8.19*). However, the higher scores on the HFS-Behavior scale for women were not statistically higher compared to the men.

An exploratory multiple regression analysis was conducted to determine the predictive influence that age and gender has on glycemic control. Specifically, a regression analysis was conducted with the predictor variables being age and gender and last glycosylated hemoglobin level (A1c) serving as the criterion variable. The overall multiple regression was significant [r^2 = .121; $b_{(Gender)}$ = -.055, *SE* = .321, *p* = .864; $b_{(Age)}$ = -.033, *SE*= .01, *p* = .002]. The relationship between current age and A1c level was significantly correlated (*r* = -.347, *p* = .001), which suggests that older participants have better glycemic control. Additionally, the relationship between age and gender was statistically significant (*r* = .328, *p* = .001), which suggests that older females and younger males were more likely to participate in the study. The F-ratio for the regression equation [*F* (2, 88) = 5.919, *p* = .004] was statistically significant which indicates that the percentage of variance accounted for by age and gender in the

glycosylated hemoglobin score was significant. The regression equation for this multiple regression analysis was [y = 8.715 - .055*(Gender)* - .033(*Age)*] with y representing the last recorded A1c level. Given that the F-ratio was significant, partial correlations were conducted to determine the impact that age has on A1c when controlling for gender. The partial correlation yielded that the degree of association between A1c level and age was significant (r = -.32, p = .002) when the effects of gender were statistically controlled. These findings suggest that age has a significant impact on glycemic control. Specifically, as one ages, glycemic control improves as measured by the A1c level.

An exploratory multiple regression was conducted to determine the impact of age and gender on the reporting of hypoglycemia-related posttraumatic stress. The predictor variables were age and gender, and the criterion variable was the PTDS severity score. The overall multiple regression was not statistically significant [adjusted r^2 = -.02; $b_{(Gender)}$ = 1.121, SE = 2.326, p = .631; $b_{(Age)}$ = -.016, SE= .076, p = .826]. When controlling for age, the mean PTDS severity score for women (M = 9.65, SD = 9.32) was approximately 1.12 points lower than their male counterparts (M = 10.60, SD = 9.22). The difference in severity score on the PTDS between men and women was not significant.

As previously mentioned, the PTDS can also be scored to provide information on whether individuals meet full diagnostic criteria for posttraumatic stress disorder as categorized by the DSM-IV. An exploratory multiple regression analysis was conducted using the PTDS diagnostic score as the criterion variable. The predictor variables were age and gender. The overall multiple regression was not significant [adjusted r^2 = -.013;

$b_{(Gender)}$ = .101, *SE* = .110, *p* = .360; $b_{(Age)}$ = -.001, *SE*= .004, *p* = .739]. A total of 23 participants (25.5%) met criteria for posttraumatic stress disorder based on the modified version of the PTDS. Of those meeting diagnostic criteria, 15 individuals (23.1 %) are women and eight participants (32 %) are men. This suggests that the probability of meeting PTSD criteria is slightly higher for men than women. However, this slight increase in probability is not statistically significant.

Additional prevalence data were collected to uncover the percentage of responding for each of the symptom clusters within the PTDS (See Table 3). As previously mentioned, the PTDS total severity score is comprised of three symptom clusters: re-experiencing, avoidance, and arousal. All chi-squares were non-significant suggesting that there were no statistical differences among men and women on each of the three symptom clusters, re-experiencing, avoidance, and arousal [χ^2 = .037, *p* = .847, χ^2 = .013, *p* = .908, χ^2 = 1.274, *p* = .259, respectively]. Men and women displayed the same trend in percentages for the symptom clusters as the overall multiple regression findings. Specifically, men endorsed higher levels than women on the avoidance cluster, 32.0 % and 30.7 %, respectively. Additionally, men endorsed more symptoms in the arousal cluster, 64.0 % and 50.7 %, compared to women. A notable exception was that women (66.1 %) endorsed slightly higher re-experiencing symptoms compared to men (64.0 %).

An exploratory multiple regression conducted to examine the predictive effects of age and gender on depressive symptoms was not statistically significant [adjusted r^2 = -.01; $b_{(Gender)}$ = -.051, *SE* = 2.427, *p* = .983; $b_{(Age)}$ = -.068, *SE*= .079, *p* = .390]. The BDI-II

score for women (M = 11.89, SD = 9.50) is approximately .051 points higher than for men (M = 11.16, SD = 10.36) when controlling for age. The higher recorded BDI-II score for women is not significant.

One final exploratory multiple regression was conducted to investigate the predictive effects of age and gender on anxiety symptomatology. The criterion variable that was used was the BAI. The overall multiple regression was not significant [adjusted r^2 = .032; $b_{(Gender)}$ = -1.10, SE = 2.22, p = .622; $b_{(Age)}$ = -.137, SE= .073, p = .063]. The relationship between age and total BAI score was statistically significant (r = -.226, p = .016). This suggests that anxiety decreases with age. Specifically, for every additional year of age, there is a .137 decrease in the BAI total score. Although this finding is non significant, it suggests that individuals may become less anxious as they age. The BAI total score for women (M = 11.26, SD =9.34) was higher than it was for men (M = 8.80, SD = 8.25) when controlling for age. However, the difference remains non-significant.

Additional Exploratory PTS Data

A t-test was conducted to compare individuals' current PTSD diagnosis on measures of depression and anxiety [t-test (1, 88) = -4.69, p = .001]. Individuals who met current PTSD according to the PTDS symptom cluster and severity scores criteria reported significantly higher BDI-II and BAI scores than participants who did not meet current PTSD criteria. Additional correlations between the PTDS total severity score and both the BDI-II and BAI were statistically significant [$r_{(BDI-II)}$ = .499, p = .001; $r_{(BAI)}$ = .633, p = .001]. This suggests that there is a positive correlation between higher scores on the PTDS and higher scores on the BDI-II and BAI.

An additional *t*-test comparing endorsement of fear of death from hypoglycemia and hypoglycemia-related PTS revealed that participants who reported fear of death from a hypoglycemic episode scored significantly higher on the PTDS total severity score than those who did not [t (1, 88) = -5.834, p = .001]. A chi-square comparing endorsement of fear of death from hypoglycemia and meeting current PTSD criteria was also significant [$\chi^2 = 18.24$, p = .001]. These results suggest that individuals who met current PTSD were more likely to also endorse a fear of death from a hypoglycemic event.

Summary of Multiple Regression Analyses

The majority of planned and exploratory multiple regression analyses yielded overall non-significant findings. However, a consistent trend displayed throughout the results was that individuals using self-injecting techniques scored higher on measures of fear of hypoglycemia, anxiety, posttraumatic stress, and, and glycosylated hemoglobin. An exception to the trend was that individuals who utilize CSII methods reported non-significantly higher levels of depression. Most notably, insulin shot users reported statistically significant higher glycosylated hemoglobin levels and behavior symptoms of FH compared to insulin pump users. An additional trend was an increase in mood and anxiety symptoms as the number of self-reported hypoglycemic episodes increased. The exceptions were a slight decrease in the behavior symptoms of FH, lower A1c levels, and overall decrease in meeting PTSD criteria as reported hypoglycemic episodes increased. The exploratory multiple regressions yielded more significant relationships between variables. Specifically, the results suggest that as one ages, anxiety significantly decreases, and glycemic control significantly improves. Additionally, women report

significantly higher levels of overall FH than men. A common trend was that women reported higher levels of mood and anxiety, and poorer glycemic control. One exception was with regards to posttraumatic stress symptoms and diagnostic criteria. The trend was for men to score higher than women.

CHAPTER 4: DISCUSSION

Despite diabetes mellitus (DM) being one of the most prevalent health concerns today, the literature examining this disorder and its medical sequelae as it relates to psychological well-being is modest. The majority of studies that have investigated diabetes and comorbid psychological phenomenon have focused primarily on establishing prevalence rates for psychiatric disorders. Overall, the data have established that individuals with diabetes have higher overall levels of mood and affective symptomatology than the general population. Notable short-comings in the research include (a) that many studies have combined samples of participants with Type I and Type II diabetes despite etiological differences among these disorders, (b) no studies have examined mood and anxiety symptoms, particularly fear of hypoglycemia (FH) among Type I individuals who utilize different intensive methods of insulin administration, and (c) no studies have examined posttraumatic stress reactions in relation to hypoglycemic episodes.

Overview

The primary focus of the present study was to elucidate the prevalence of affective and anxiety symptomatology among individuals with Type I DM who utilize two different intensive management regimens: a minimum of 3 insulin shots daily or continuous subcutaneous insulin infusion (CSII). Furthermore, research has demonstrated that individuals who report less depressive and anxiety symptoms display better glycemic control (maintaining a blood glucose levels with normal limits) than their counterparts who endorse psychological distress. Longitudinal studies have

demonstrated that individuals who utilize intensive insulin regimens are at increased risk for hypoglycemia due to the reduced margin of error associated with tighter glycemic control (DCCT, 1993). Therefore, an additional focus of this present study was to examine whether glycemic control impacts endorsed levels of mood and anxiety symptoms among a Type I population using intensive exogenous insulin administration.

PTSD Findings

There has been increased attention in the behavioral medicine literature to the concept of posttraumatic stress (PTS) symptoms in individuals with medical conditions. The rationale is that receiving a diagnosis and/or medical complications related to the diagnosis may be sufficient to meet the DSM-IV criteria of a traumatic event. Specifically, a life threatening medical diagnosis and/or its related complications may serve as an actual or perceived threatening event that is traumatic to the individual. Subsequently, the individual may respond to his/her medical threat with feelings of fear and helplessness.

As previously mentioned, the most extensive line of research in the area of PTS and medical complications has been conducted on individuals with cancer. The data show that these individuals have elevated rates of PTS symptoms. Additional studies have also demonstrated elevated PTS symptoms in other non-cancer related medical disorders. These studies demonstrate that health-related complications and medical diagnoses are sufficient to qualify as traumatic events in some individuals. Furthermore, studies have also demonstrated that vicarious traumatization may occur in family members of individuals with medical complications. In a recent study by Alderfer,

Labay, and Kazak (2003), for example, 49 % siblings of children with cancer reported mild PTS symptoms. To date, only one study has examined the relationship between diabetes mellitus (DM) and posttraumatic stress. Specifically, a study by Landolt and colleagues (Landolt et al., 2002) demonstrated high posttraumatic stress rates in parents of children newly diagnosed with Type I diabetes. However, there are no PTS data on individuals with DM despite evidence that individuals who experience increased FH also experience elevated levels of perceived stress and anxiety. Therefore, this study is the first of its kind to examine the impact of hypoglycemic episodes related to DM as a potential source of PTS symptoms.

One of the goals of this study was to assess further the impact of hypoglycemia-related experiences that may relate to posttraumatic stress. Regardless of age or method of administration, 30 % of the total sample reported fear of death from hypoglycemia, 81.1 % required assistance from someone else during a low BG episode, 25.6 % experienced a low BG seizure, 45.6 % experienced loss of consciousness due to low BG, 46.7 % required paramedic assistance, 38.9 % required a trip to the emergency room, 20 % reported a diabetes-related hospitalization, and 11.1 % reported having a low BG related automobile accident. Therefore, these hypoglycemia-related experiences may have served as a traumatic setting event for some of the individuals due to the increase fear and sense of helplessness that may accompany such events. Specifically, on the PTDS, individuals were asked to identify a low blood sugar episode that was particularly frightening. Often participants would report experiences such as loss of consciousness, a seizure, or “waking up” with the paramedics there, etc.

One of the primary hypotheses of this study was to ascertain whether method of insulin administration predicts the endorsement of hypoglycemia-related posttraumatic stress symptoms. Although the overall finding was non-significant, the prevalence rates endorsed are noteworthy and merit further discussion (See Table 3). Specifically, for the total sample, 25.5 % met diagnostic criteria for PTSD. This suggests that regardless of method of administration, 1 out of 4 individuals with Type I DM in this sample have diagnosable current PTSD based on the PTDS scale. There are no prevalence data on PTSD and diabetes to compare to these findings. However, the rate appears to be comparable to the cancer and PTSD literature which ranges from 3 % to 21 % (Boyer et al., 2002).

Furthermore, 38.4 % of self-injectors compared to 23.3 % of those on an insulin pump met criteria for current PTSD. Overall, the comparison of the two groups was not statistically significant. However, the magnitude of the difference between the two groups (i.e., 15 %) is noteworthy. However, it is unclear why those individuals on a pump met criteria less frequently than those using shots. Based on this sample, men were more likely to endorse posttraumatic stress symptoms and to meet current PTSD criteria. Specifically, the percentage of women meeting PTSD criteria based on the PTDS was 23.1 %, whereas it was 32 % for men. This finding is fairly surprising given that prevalence data suggest higher prevalence of PTSD in women than men (Tolin & Foa, 2002). However, research suggests that men experience more trauma events, but women are more likely to develop PTSD (Gavranidou & Rosner, 2003), and that prevalence rates

of PTSD in men compared to women has been higher for certain types of traumas (Resick & Calhoun, 2001).

The data revealed high prevalence rates for the PTSD symptom clusters as measured by the PTDS. As previously mentioned, the PTDS total severity score is comprised of three symptom clusters: re-experiencing, avoidance, and arousal. Specifically, within the total sample, nearly two-thirds (65.5 %) met criteria on the re-experiencing cluster, one-third (31.1 %) met criteria for avoidance symptoms, and over half (54.4 %) met criteria for the arousal cluster. This suggests that a large percentage of the total sample may be experiencing emotional distress in each of these domains, but may not meet full current diagnostic criteria. Among the insulin pump users and self-injectors, 69.2 % of self-injectors and 64.9 % of insulin pump users met criteria for re-experiencing symptoms. The difference between the two groups was not statistically significant, and the overall difference in magnitude was small (i.e., 4 %). However, it is the overall trend of the re-experiencing data regardless of method of insulin administration that is so compelling. These data are concerning because a significant portion of this sample is indicating that the fear of a hypoglycemic episode is producing symptoms such as intrusive thoughts, distressing dreams, or intense physiological reactivity to cues of FH. It is possible that the feelings that the hypoglycemic event is recurring may be linked to overreaction to daily fluctuations in blood sugar, or the common occurrence of nocturnal hypoglycemia.

The self-injectors may have endorsed slightly higher, non-significant levels of re-experiencing due to the insulin regimen that they use. Specifically, individuals who use

self-injection methods must manage and combine the use of various types of insulin. Different types of insulin include rapid-acting (starts working 5 minutes after injection and peaks in approximately an hour), regular/short-acting (reaches the bloodstream in about an 30 minutes, and peaks approximately 2 to 3 hours later), intermediate-acting (reaches the bloodstream in approximately 2 to 4 hours and peaks 4 to 12 hours later) and long-acting (reaches the bloodstream 6 to 10 hours after injection and usually is effective for 20 to 24 hours). An individual who uses self-injection methods must manage the different amounts of the various insulin types, (e.g., short-acting insulin (bolus amount for when they eat), and long-acting insulin (basal amount to maintain consistent slow releasing insulin) throughout the day). Insulin pumps can deliver a continuous drip of insulin (basal dose) all day long. It is possible to pre-program several basal doses depending on the needs of the individual, and additional amounts of insulin (bolus dose) can be distributed at the push of a button. It may be that self-injectors are slightly more likely to have psychological distress, which is perceived as re-experiencing, when they begin to have the internal or physical cues that their insulin and BG levels are not optimal. Additionally, it may be that the self-injectors have more tedious monitoring of their peak times on the different types of insulin which serves as a continual stressor and increases vigilance. Specifically, self-injectors must remember to consume food several hours later to cover the impact of their long-acting insulin taken 6 to 8 hours earlier. Otherwise, they risk having a hypoglycemic episode. Insulin pump users also require vigilance for their regimen. They must be vigilant of how much insulin is in the pump reservoir, change infusion site every couple of days, etc. However, it may be that the

close monitoring of the various acting times of the different insulin types is more tedious and time-consuming for self-injectors, and increases the risk of injecting too much insulin, too soon. This in turn increases the frequency of hypoglycemia which may increase the likelihood of re-experiencing intense psychological and/or physiological distress at exposure to hypoglycemic states. Overall, this is purely speculative particularly since the difference between the insulin pumps users and self-injectors was statistically non-significant.

Additionally, among the self-injectors, 38.4 % endorsed avoidance symptoms compared to 29.8 % of insulin pump users. The avoidance symptoms may include thoughts and behaviors to avoid feelings of hypoglycemia, inability to recall important aspects of previous hypoglycemic states, and diminished interest or feelings of estrangement. The overall difference between the two groups was not statistically significant. However, the magnitude of difference between the groups, 9 %, suggests a trend of higher responding among self-injectors. It is unclear why self-injectors report greater symptoms than the pump users. It is plausible that the self-injectors have decreased cognitive awareness for hypoglycemic states thus impairing their ability to recall important aspects of previous hypoglycemic states. Also, self-injectors and insulin pump users both must continually monitor blood sugar levels and adjust insulin levels accordingly. This process may make these individuals feel more detached from others. Self-injectors may feel more estranged from the individuals around them compared to pump users because self-injectors may have to quickly inject insulin using a needle while in public. Insulin pump users have slightly more discretion with supplying themselves

with insulin. Specifically, the insulin pump is small, portable, already in place, and can appear to be a pager to the naïve eye.

Also of note, 69.2 % of the self-injectors compared to 51.9 % of the insulin pump users endorsed arousal symptoms. The arousal symptoms could include difficulty falling asleep, poor concentration, and hypervigilance. Once again, the overall difference was not statistically significant. However, the magnitude of the difference, 18 % is noteworthy. It is unclear why the self-injectors have increased levels compared to insulin pump users. However, returning to the notion of insulin regimen, it may be that self-injectors perceive the need to be more hypervigilant regarding their insulin states since their insulin amounts are not pre-programmed like the insulin pump, and therefore, they must maintain keen awareness of when they may need insulin, or when they may have too much in their system. Furthermore, it is plausible that this regimen may pose demands on the individual that are not functionally related. Specifically, the self-injectors may feel anxious and reactive due to intrusive memories of prior hypoglycemic episodes even in the absence of the logical need to do so.

Percentage rates were also calculated to compare men and women on the PTDS symptom clusters. Overall, men and women did not statistically differ from one another on any of the symptom clusters. Specifically, men endorsed slightly higher levels than women on the avoidance cluster (32.0 % and 30.7 %, respectively). However, the magnitude of the difference was nominal. Additionally, men endorsed more symptoms in the arousal clusters, 64.0 % and 50.7 %, compared to women, which suggests that men

may experience more irritability, hypervigilance, or concentration problems regarding their diabetes.

Overall, these findings suggest that hypoglycemia-related PTS phenomenon as it relates to diabetes is complex, yet compelling. Given that the overall tests of significance were not statistically significant, it is not clear how method of administration and gender may specifically impact symptom cluster endorsement for PTSD. However, the larger magnitudes of differences between insulin pump users and self-injectors on the avoidance and arousal clusters, as well as the percentage difference between the genders on the arousal cluster suggest that individuals with diabetes may experience specific symptom clusters of PTSD depending on their gender and insulin regimen. Overall, these findings support previous research data on PTS symptoms in individuals with medical conditions, and further demonstrate that health-related complications and medical diagnoses appear to be sufficient to qualify as traumatic events in certain individuals.

Although the PTS findings are interesting, one should caution about overinterpreting the prevalence of PTSD among this sample. Specifically, there are several contentious issues in the field of posttraumatic stress (e.g., the definition of trauma, distortion in recollection of trauma, risk factors) that should be considered when conducting research and making a clinical diagnosis of PTSD. For a full and balanced review of these issues, the reader is referred to McNally (2003) and Sageman & Herbert (in press). Specific to this study, concerns over what defines a trauma and the impact of psychological distress on self-report needs to be addressed.

Criterion A for Posttraumatic Stress Disorder in the DSM-IV delineates that an individual must be exposed to a *qualifying* traumatic stressor in order to meet the DSM-IV diagnosis. Criterion A as it is written defines a traumatic exposure as "the person experienced, witnessed, or was confronted with an event that involved actual or threatened death." This suggests that not only an actual threat, but a *perceived* threat can qualify as a traumatic stressor. This broadening of what is considered a stressor introduces a slippery slope in which normal and appropriate psychological responses to stressful situations may be misinterpreted and codified as a trauma. Specifically, the criterion as written fails to discriminate between true symptoms of PTSD and normal distress responses. For example, for this sample, participants who reported fear of death from a hypoglycemic episode scored significantly higher on the PTDS total severity score and met PTSD criteria according to the PTDS more frequently than those who did not fear death. These results suggest that individuals who met current PTSD were more likely to also endorse a fear of death from a hypoglycemic event. Individuals with DM can die from a hypoglycemic coma, so an element of actual threat is present. However, it is more likely that the fear of death is more distressing to individuals rather than an actual threat. This suggests that the diagnosis of PTSD may be driven by the *perception* of the threat of death rather than an actual threat. In turn, this can result in a diagnosis of PTSD based on a fear of what might happen rather than what has actually occurred.

Additionally, the impact of psychological state on self-report is not sufficiently addressed in the DSM-IV criteria for PTSD. Specifically, the diagnosis of PTSD is only as accurate as the individual's self-report, and there is evidence that psychological state

can impact how a traumatic event is remembered (McNally, 2003). Namely, the more psychological distress an individual is experiencing whether it is causally related to the traumatic event or not, the higher the likelihood that PTS will be endorsed. In this study, individuals who met current PTSD criteria reported significantly higher BDI-II and BAI scores than participants who did not meet current PTSD criteria. Additionally, correlations between the PTDS total severity score and both the BDI-II and BAI were statistically significant suggesting that there is a positive correlation between higher scores on the PTDS and higher scores on the BDI-II and BAI. Therefore, for this sample, it may not be that individuals in this study had high rates of PTSD because of specific hypoglycemic events that were traumatic, rather it is plausible that individuals who endorsed PTS symptoms were more likely experiencing elevated mood and anxiety symptoms. In turn, the depressive and anxiety symptoms may have caused the recollection of hypoglycemic events to be perceived as more life threatening and thus interpreted as more severe or traumatic. Regardless of the etiology of the recollection, the issues of what defines trauma and the impact of psychological state suggest that interpretation of the PTS data should be done with caution.

Methods of Administration: Demographic Differences

An additional objective of this study was to further characterize differences based on demographic information among the two intensive insulin regimens. A consistent trend among the demographic data revealed that insulin shot and pump users varied in who endorsed higher rates of many of the items in each of the conceptual clusters. As previously mentioned, the dependent variables were theoretically clustered into seven

conceptual clusters, and Bonferroni corrections were calculated for each cluster (see Table 1). The majority of comparisons were not statistically significant. One of the most compelling features of these data are the percentage rates obtained for commonly experienced situations among people with diabetes. As previously mentioned, of notable interest is that the total sample experienced high levels of various hypoglycemic experiences (i.e., at least one hypoglycemic episode, fear of death from hypoglycemia, required assistance from someone else during a low BG episode, etc). Additionally, the sample endorsed high levels of certain medical complications (i.e., 42.2 % reported vision problems, and 26.7 % reported neuropathy problems, etc). Insulin shot users consistently endorsed higher rates of long-term hyperglycemia consequences (i.e., blindness, amputations, and strokes), as well as less suddenly life-threatening complications (i.e., fear of hypoglycemic death, employment reprimands, requiring assistance from others than pump users). Whereas, pump users were more likely to endorse sudden medical consequences/emergencies related to hypoglycemia compared to shot users (i.e., lowest blood sugar recording, number of LOCs due to hypoglycemia, low BG-related automobile accidents, trips to the ER, low BG and DM hospitalizations). Interestingly, within all of the conceptual clusters only one variable was marginally significant, the rest were non-significant. Specifically, there was a marginally significant difference between pump users and self-injectors for neuropathy problems with pump users endorsing more diagnosed neuropathy than insulin shot users. This is particularly interesting, since for the most part, insulin shot users endorsed more long-term hyperglycemia problems than pump users, and neuropathy is a medical complication of

uncontrolled hyperglycemia. Furthermore, insulin shot users endorsed more diabetes-related amputations and strokes than insulin pump users, both complications of which are circulatory problems. This suggests that perhaps pump users have experienced more specifically diagnosed neuropathy problems and critical low BG emergencies than their self-injecting counterparts, whereas insulin shot users have more hyperglycemia complications. However, one should caution against overgeneralizing these points, and specifically trying to pigeon-hole pump users and insulin shot users into defined categories of medical complications. Although statistically non-significant, pump users tended to be somewhat older than the self-injectors. Therefore, the differences between the methods of administration for medical complications may be secondary to a disease process. Specifically, as people with diabetes age, they report more medical complications as the disease progresses. Therefore, the differences between the insulin regimens may not be due to the regimen itself, but rather the progression of diabetes. Additionally, the average length of pump use for the sample was approximately four years, which implies that those currently on the pump switched from self-injecting methods around the age of 40 years. It could be that individuals currently using CSII methods transitioned from self-injection methods at the onset of some of the aforementioned medical complications. Specifically, the onset of various medical complications may have acted as the catalyst for switching to an insulin pump regimen. One limitation of this study was that participants were not instructed to report which method of administration they were utilizing at the time they first started having these complications. It is possible that the switch from self-injecting methods to insulin pumps

served to arrest further development of medical complications that initially began while using insulin shots.

Mood and Anxiety Findings

It was hypothesized that method of administration would predict mood and anxiety symptomatology. Specifically, it was postulated that research participants who utilize insulin pumps would report significantly higher levels of mood and anxiety symptoms. The majority of the analyses yielded non-significant findings. However, a common trend that emerged was that the self-injecting group scored higher on measures of fear of hypoglycemia (FH), anxiety, posttraumatic stress (PTSS), and displayed poorer glycemic control compared to those participants who use insulin pumps. A notable exception was that insulin pumps users reported non-significantly higher scores for depression. Although these findings are non-significant, they are worth mention, because these findings suggest that depression may not be as prevalent as previously reported in the diabetes literature.

Previous research has suggested that individuals who utilize insulin pumps report increased flexibility and overall improved quality of life (Wolf et al., 1989). Although not systematically assessed in this study, the low scores for mood and anxiety symptoms displayed by the insulin pump group and self-injectors may reflect the participants' overall satisfaction of life quality secondary to insulin regimen. With regard to depression among this sample, both groups reported BDI-II scores in the *minimal depression* range and there was less than a one point difference in total score between the two groups. Of interest is the fact that several studies have demonstrated a strong trend

of depression among people with diabetes. Specifically, it has been estimated that 1 in 5 individuals with diabetes is clinically depressed, and that 40 % of individuals with DM have significantly elevated levels of depression, but are not clinically depressed (Garvard et al., 1993). All of these studies have used combined samples of individuals with Type I and Type II DM. Given that this research sample did not display the high rates of depressive symptoms found in the literature, and was unique in that it contained only persons with Type I diabetes, this suggests that overall estimates of depressive symptoms in the diabetes literature may be an artifact of individuals with Type II diabetes having disproportionately higher levels of depression compared to those with Type I diabetes.

Additionally, studies have demonstrated that individuals with DM may misinterpret or have a diminished capacity to differentiate between anxiety and symptoms of poorer glycemic stability (i.e., hypo-or hyperglycemia) (Jacobson, 1996; Lustman, 1988). Specifically, individuals may misinterpret symptoms of hypo- or hyperglycemia as that of anxiety. In this research sample, the insulin pump users displayed better glycemic control than their self-injecting counterparts. Therefore, the relatively lower level of anxiety symptoms may reflect the good glycemic stability among the pump users. The insulin pump users reporting slightly higher depression scores relative to lower anxiety scores compared to self-injectors may be related to the insulin regimen used. Specifically, since insulin pump users can pre-program their pumps to maintain a continuous drip of insulin at all times, and thus avoid a potential sudden BG drop, they may perceive less stress or anxiety regarding potential hypoglycemia. Therefore, it may be that insulin pump users and self-injectors have

similar levels of depression, but the pump regimen provides for some type of protection against anxiety which is inherent to the regimen.

Exploratory Age and Gender Findings

Additional exploratory analyses revealed compelling data regarding the predictive influence of age and gender on the mood and anxiety symptoms of interest. These results suggest that as one ages, anxiety and depressive symptoms decrease, and glycemic control significantly improves. This was a surprising finding particularly given that many of the assessment tools used are heavily loaded for somatic items. Traditionally, as a person ages they experience many of the physical pains associated with a deteriorating body. These physical complaints can often times be inadvertently endorsed on psychological assessment tools, particularly those items loaded towards physical complaints (Lustman, 1988). However, that trend was not displayed in this study. The sample in this study was relatively young (i.e., middle-aged), and may not have the physical complaints often seen with geriatric populations. This trend may be influenced by the fact that glycemic control significantly improved with age. Specifically, better glycemic control may act as a buffer against mood and anxiety symptoms, because the individual may experience less hyperglycemia related medical risks. This in turn results in less physical complaints and improved psychological well-being. Furthermore, it is plausible that as people with DM age they may become more accepting of their disease resulting in an overall decrease in depressive and anxiety symptoms related to diabetes.

Not surprisingly, the trend was for women to endorse overall higher levels of mood and anxiety symptoms and poorer glycemic control than men based on the

measures administered. Most notably, of all the mood and anxiety measures, women endorsed significantly higher rates of fear of hypoglycemia, as measured by the HFS-98 Total and HFS-Worry scores. Given the trend for women to have poorer glycemic control it is surprising that the HFS-Behavior subscale was not significantly different between the genders. Specifically, this scale assesses for behavioral symptoms of FH, including running blood sugar levels too high in order to avoid hypoglycemia. Given that women had poorer glycemic control and higher levels of FH it would not be unreasonable to assume that women's higher A1c levels may be related to overcompensating a fear of low BG by maintaining higher BG levels. The data suggest that women report greater FH and worry about hypoglycemia.

Study Strengths and Limitations

A notable limitation of this study was the significant differences on the variables of age, gender, and method of administration between participants and nonparticipants. Specifically, the participants in the study were significantly older, more likely to be female, and more likely to use an insulin pump compared to all the individuals in the solicitation sample. In the original solicitation sample, the ratios of males-to-females and number of self-injecting individuals-to-insulin pump users were fairly balanced. Therefore, it is unclear why individuals who were older, and/or female, and who use an insulin pump were significantly more inclined to participate in this study. It could be that the slightly older individuals were more likely to participate in the study because of increased available time to devote to the study, or increased motivation to participate based on interest in furthering the knowledge about diabetes. The majority of the

assessment tools used have been examined with various age ranges, and none have data reporting that there has been improved responding among individuals over the age of 40 years compared to adults under the age of 40 years. Regardless, this remains speculative and there is no clear explanation for the age difference in responders versus non-responders. The finding that females were more likely to participate in the study is not surprising. Traditionally, women have been more likely to participate in psychological research as well as seek psychological help compared to men (Moeller-Leimkuehler, 2002). Given the face validity of the assessment items as well as the solicitation letter that explained that this study was examining psychological well-being among individuals with diabetes, it may be that men were less likely to initially be inclined to participate. Despite the number of male participants being smaller, nonetheless interesting gender effects did emerge. Namely, the men in this sample were more likely to use an insulin pump, were more likely to met criteria for PTSD based on the PTDS, and had slightly better glycemic control than their female counterparts. However, one should caution about overinterpretation given the overall non-significant findings.

The most striking limitation of the responder versus non-responder data was the discrepancy between the number of participants utilizing self-injecting methods compared to those using insulin pumps. Given that the principal aim of this study was to examine differences among the methods of insulin administration, this is a concern that requires cautious interpretation of the entire study data. Interestingly, the initial solicitation sample obtained from Integrated Diabetes Services (IDS) was fairly evenly split in the ratio of pump users-to-self-injectors. Additionally, a second follow-up

telephone call was made to individuals who use self-injecting methods to prompt participation and provide further details of the study. However, this second follow-up telephone call placed two weeks after the originally planned follow-up call was executed did not significantly increase the number of participants. It is unclear why individuals who use CSII methods were more inclined to participate. It is possible that insulin pump users found something intrinsically interesting about the study, or that they felt inclined to assist IDS, or were interested in perpetuating the knowledge of diabetes to be furthered. It could be further hypothesized that this group felt and/or perceived themselves to be more psychologically well and were therefore less ashamed or afraid of being stigmatized thus increasing likelihood of participation. Regardless, there is no clear explanation for the discrepancy between the sample sizes. Additionally, the difference in the sample sizes draws into question the generalizability of these findings to the larger diabetes population. Only 26 % of the original solicitation sample chose to participate in the study which suggests that the representativeness of this sample to the overall Type I diabetes population is suspect. Only 13 participants, 14.4 %, utilized a self-injecting regimen. The majority of comparisons among the insulin shot users and pump users were non-significant, but data trends suggested better management among pump users. It is plausible that the comparisons between insulin regimens yielded non-significant findings because the insulin shot users may have been unusually well-trained in their DM management and adherence that any differences between regimens was minimized. Specifically, participants in this study were intensely educated about their diabetes, and provided state-of-the-art training on their intensive insulin regimens by

trained certified diabetes educators. Additionally, participants were regularly followed by IDS which included regular glycosylated hemoglobin screenings, and additional management training as needed if glycemic control was poor. Additionally, the glycemic control for both insulin pump and insulin shot users was within normal ranges which suggests that a selection bias may have occurred because individuals with especially good glycemic control were more likely to participate in the study. Therefore, the shot users may have been an "elitist" group compared to other shot users regarding DM management which resulted in an inability to detect significant differences between insulin regimens.

Although the discrepancy between the insulin pump users and self-injectors was large, the researchers did not contemplate increasing the sample size of the self-injectors by seeking participants outside of IDS for several reasons. Most notably, one strength of this study was the uniformity and size of the solicitation sample. Of the 344 participants solicited, each had received extensive training on diabetes management, and the sample was therefore most likely better trained at maintaining their glycemic stability than others who received diabetes education from non-diabetes educators. If the researchers had sought out self-injecting Type I individuals outside of IDS there would have been no guarantee or control of level of diabetes management training of the participant. Additionally, the researchers would have been unable to control for other differences such as demographics, overall medical status, and socioeconomic status by obtaining an outside sample. Therefore, a selection bias would have been introduced, and would have yielded less reliable data.

Despite the limitations of this study, there were several noteworthy strengths. This study relied heavily on a convenience sample (i.e., IDS solicitation sample). Typically, convenience samples can yield small, non-representative groups. Several strategies in this study were implemented for increasing successful participant recruitment. Specifically, (a) staff and administration at Integrated Diabetes Services (IDS) provided support and were actively involved in outreach to participants, (b) potential participants were assured that participation was voluntary and that participating or not participating would not improve or adversely affect their care at IDS due to blindness of the staff and administration, (c) the design of the study via multiple contacts with participants may have acted to increase the relevance and importance of the study to the participants, (d) a monetary incentive was provided for participation via a lottery, (e) the mailed survey went directly to potential participants and therefore facilitated the inclusion of individuals who may not maintain regularly scheduled appointments with IDS, and (f) the assessment protocol was limited and focused rather than using a large battery of questionnaires which may fatigue and discourage individuals from participating.

Additional strengths of this study included that the sample obtained was unique compared to other studies of psychological wellness and diabetes. Namely, this study focused on isolating and identifying mood and anxiety symptomatology among individuals with Type I DM. Prior studies have used combined samples of individuals with Type I and Type II DM despite etiological differences. Furthermore, no studies to date have examined differences among individuals using different methods of insulin

administration. The results suggest that overall individuals using continuous subcutaneous insulin infusion (CSII) methods may have less mood and anxiety than their self-injecting counterparts. Additionally, this study is the first of its kind to provide a direct examination of fear of hypoglycemia (FH) and hypoglycemia-related posttraumatic stress among Type I individuals using different intensive insulin administration methods.

Future Directions

Additional data are needed to elucidate further the role of method of administration and glycemic stability in mood and anxiety symptomatology among Type I DM individuals. Future studies should focus on increasing the sample size in order to increase statistical power. This in turn would provide more conclusive findings rather than data based on trends. Regarding glycemic stability and number of reported hypoglycemic episodes, this study suggests that women have poorer glycemic control as measured by glycosylated hemoglobin and more monthly hypoglycemic episodes. In a study assessing psychological symptoms, perceived stress, risk of hypoglycemia, and glycemic control among Type I individuals, daily blood glucose variability was related to cognitive symptoms of FH (Irvine, Cox, Gonder-Frederick, 1992). Specifically, it was found that individuals with lower mean daily BG and higher BG variability were more fearful of hypoglycemia. A future direction of this study would be to include self-monitoring logs of daily BG readings as a potential predictor of mood and anxiety. Furthermore, each method of administration technique may have unique demands inherent to the regimen (i.e., monitoring length of time since last basal amount of long-lasting insulin, programming a pump regularly, making sure injectable insulin is readily

available, new batteries for insulin pumps, etc.). Therefore, future studies may want to concentrate on whether demands that are uniquely inherent to the administration regimen used impact psychological well-being. Additionally, assessing further the impact of age, motivational factors for participating in the study, gender differences, and focusing on the point in time were individuals transitioned from self-injecting to CSII methods may clarify some of the trends noted in this study.

Overall, this study accomplished several of its primary goals despite discrepant sample sizes. Specifically, the nature of mood and anxiety symptomatology and relative differences among Type I individuals using different intensive methods of insulin administration were revealed. Furthermore, the impact of method of administration and hypoglycemic experiences on fear of hypoglycemia were systematically investigated. Finally, hypoglycemia-related posttraumatic stress was examined, and it was revealed that 1 out of 4 participants met diagnostic criteria for current PTDS, with men representing a higher proportion than women. This provides evidence that for a subset of individuals with Type I diabetes, the medical sequelae associated with hypoglycemic states is sufficient enough to qualify as a traumatic event.

Table 1: Comparisons of Methods of Administration by Data Clusters
Using Chi-Squares and T-tests

			Percentages	
Theoretical Cluster	χ^2 / *t* value	*p* value	Shots	Pumps
Cluster 1: Demographics				
Current age		.056	36.5 yrs	44.4 yrs
Age when first diagnosed		.969	20 yrs	19.8 yrs
Gender	.167	.682		
Female:			76.9 %	71.4 %
Male:			23.1 %	28.6%
Female:Male	17.78*	.001		
Race/Ethnicity	.792	.374		
Caucasian:			84.6 %	92.2 %
Caucasians:Non-Cauc.	285.11*	.001		

* $\underline{p} < .001$

Table 1 (*continued*)

Theoretical Cluster	χ^2 / *t* value	*p* value	Percentages	
			Shots	Pumps
Cluster 2: Cognitive Awareness of Low BG				
Low BG level ever	.345	.557	100 %	97 %
Lowest BG recorded (mg/dl)		.473	29	27
Fear of Death	1.888	.169	46.2 %	27.3 %
* p < .0125 (Bonferroni correction)				
Cluster 3: Consequences of sudden low BG				
Automobile Accidents	.180	.672	7.7 %	11.7 %
Employments Reprimands	2.092	.148	7.7 %	1.3 %
Assistance from Others	.122	.727	84.6 %	80.5 %
* p < .016 (Bonferroni correction)				

Table 1 (*continued*)

Theoretical Cluster	χ^2 / *t* value	*p* value	Percentages: Shots	Percentages: Pumps
Cluster 4: Sudden Medical Consequences of Low BG				
Hypoglycemic Seizure	.049	.825	23.1 %	26.0 %
Loss of Consciousness	.308	.579	38.5 %	46.8 %
Paramedic Assistance	.002	.968	46.2 %	46.8 %
Trip to the ER	3.532	.06	15.4 %	42.9 %
Hypoglycemic Hospitalizations		.178	15.4 %	19.5 %
* p < .0125 (Bonferroni correction)				
Cluster 5: Diabetes-related Vision Problems				
Blindness	2.092	.148	7.7 %	1.3 %
Vision changes	2.283	.131	23.1 %	45.5 %
* p < .025 (Bonferroni correction)				

Table 1 (*continued)*

Theoretical Cluster	χ^2 / *t* value	*p* value	Percentages: Shots	Percentages: Pumps
Cluster 6: Comorbid Complications				
Kidney Problems (ESRD)	.000	.990	7.7 %	7.8 %
Cardiac Problems	.000	.990	7.7 %	7.8 %
"Other" Complications	.411	.521	15.4 %	23.4 %
DM-related Hospitalizations	1.439	.230	7.7 %	22.1 %
* p < .0125 (Bonferroni correction)				
Cluster 7: Circulatory System Complications				
DM-related Amputations	.896	.344	7.7 %	2.6 %
DM-related Stroke	2.798	.094	15.4 %	3.9 %
Neuropathy	5.525	.019*	0.0 %	31.2 %
*p < .016 (Bonferroni correction)				

Table 2: Summary of Multiple Regression Analyses for
Method of Insulin Administration and Hypoglycemic Episode

	Method of Administration		Hypoglycemic Episodes	
Measure	B	SE	B	SE
HFS-98 Total:	9.638	.174	.141	.572
HFS-98 Worry:	5.514	4.042	.188	.169
HFS-98 Behavior:	4.124	2.424	-.047	.101
Fear Composite Score:	2.701	4.196	.080	.176
Last Alc:	.903	.419	.003	.017
PTDS Severity:	3.396	2.813	.070	.118
PTDS diagnostic:	.143	.133	-.001	.006
BDI-II:	-.501	2.952	.003	.124
BAI:	5.367	2.713*	.011	.114

* $p < .05$

Table 3: Participants' Posttraumatic Stress Symptomatology

	Percentages				
	Total Sample	Self-Injectors	Pump Users	Men	Women
Current PTSD Criteria					
	25.5 %	38.4 %	23.3 %	32.0 %	23.1 %
PTSD Symptom Clusters					
Re-experiencing Symptoms					
	65.5 %	69.2 %	64.9 %	64.0 %	66.1 %
Avoidance Symptoms					
	31.1 %	38.4 %	29.8 %	32.0 %	30.7 %
Arousal Symptoms					
	54.4 %	69.2 %	51.9 %	64.0 %	50.7 %

Table 4: Summary of Multiple Regression Analyses for Gender and Age

	Gender		Age	
Measure	B	SE	B	SE
HFS-98 Total:	-8.750	4.832	-.006	.158
HFS-98 Worry:	-5.962	3.282	-.049	.107
HFS-98 Behavior:	-2.788	2.002	.042	.065
Fear Composite Score:	-5.434	3.441	-.071	.113
Last Alc:	-.055	.321	-.033	.010*
PTDS Severity:	1.121	2.326	-.016	.076
PTDS diagnostic:	.101	.110	-.001	.004
BDI-II:	-.052	2.427	-.068	.079
BAI:	-1.10	2.222	-.137	.073

* $p < .05$

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Appendix A: Demographics

1. What is your date of birth? ___/___/____
   Mo/day/year

2. What is your current age? _____

3. What is your gender? _____ female _____male

4. What is your race/ethnicity?
   _____ Caucasian
   _____ Black/ African-American
   _____ Hispanic
   _____ Asian
   _____ Native American
   _____ Other, please specify _____

5. When were you first diagnosed with Diabetes? ___/___/____
   Mo/day/year

6. Age when first diagnosed with Diabetes _____

7. Where you diagnosed with Type I or Type II Diabetes? _____Type I
   _____Type II

8. Which method of insulin administration do you use?
   _____ Insulin pump _____ Daily injections

9. If applicable, when did you first start using an insulin pump? ___/___/____
   Mo/day/year

10. If applicable, how many injections of insulin do you give a day? _____

11. What is your ratio for units of insulin per grams of carbohydrate?
    _____ (ratio) _____Don't Know _____Don't Have One

12. What is your ratio for units of insulin for number above your goal blood sugar?
    _____ (ratio) _____Don't Know _____Don't Have One

13. Do you use temporary basal rates for high fat foods? ____yes ____no

14. What was your last hemoglobin A1c value? _____

15. Date of your last hemoglobin A1c value? ___/___/____
Mo/day/year

16. Please check any of the following complications that you have experienced:
_____Blindness
_____ESRD; kidney failure
_____Neuropathy
_____Stroke
_____Myocardial Infarction; Heart Problems
_____Amputation
_____Vision changes/retina problems
_____Other, please specify
_____

17. When did you last see an ophthalmologist? ___/___/____
Mo/day/year

18. Have you ever had an episode of low blood sugar? _____yes _____no

19. What was the lowest blood sugar you've ever recorded when testing? _____
When was this? ___/___/____
Mo/day/year

20. Check any of the following things that have happened to you when your blood sugar has gotten low:
a) Pass-out or become unconscious _____yes _____no
b) Require help from a friend, family member/stranger _____yes _____no
c) Need assistance from paramedics _____yes _____no
d) Been hospitalized _____yes _____no
e) Go to the emergency room _____yes _____no
f) Had a seizure from low blood sugar _____yes _____no
g) Had an automobile accident _____yes _____no
h) Was formally reprimanded or fired from job _____yes _____no

21. Have you ever had a hypoglycemic episode in which you feared that you would die from low blood sugar? _____yes _____no

22. How many episodes of low blood sugar have you had in the past month (times you needed to eat something quickly to bring you blood sugar up from a low level)?
_____

23. How many times have you been hospitalized for low blood sugar? _____

24. How fearful are you of low blood sugar?

1	2	3	4	5	6	7
Not at all frightened						Extremely frightened

25. How much of the time do you think or worry about low blood sugar?

1	2	3	4	5	6	7
Not at all						All the Time

26. How much does fear of low blood sugar affect your activities to manage your blood sugar?

1	2	3	4	5	6	7
Not at all						Extremely

27. How much do you avoid activities, situations, or places due to fear of low blood sugar?

1	2	3	4	5	6	7
Not at all						Extremely

28. How fearful are you of blindness related to diabetes?

1	2	3	4	5	6	7
Not at all frightened						Extremely frightened

29. How fearful are you of kidney failure related to diabetes?

1	2	3	4	5	6	7
Not at all frightened						Extremely frightened

30. How fearful are you of neuropathy related to diabetes?

1	2	3	4	5	6	7
Not at all frightened						Extremely frightened

31. How fearful are you of stroke related to diabetes?

1	2	3	4	5	6	7
Not at all frightened						Extremely frightened

32. How fearful are you of myocardial infarction/heart problems related to diabetes?

1	2	3	4	5	6	7
Not at all frightened						Extremely frightened

33. How fearful are you of amputation related to diabetes?

1	2	3	4	5	6	7
Not at all frightened						Extremely frightened

34. How fearful are you of vision changes/retina problems related to diabetes?

1	2	3	4	5	6	7
Not at all frightened						Extremely frightened

Appendix B: HFS-98

I. Behavior: Below is a list of things people with diabetes sometimes do in order to avoid low blood sugar and its consequences. Circle one of the numbers to the right that best describes what you have done during the past 6 months in your daily routine to AVOID low blood sugar and its consequences.
(Please do not skip any!)

	Never	Rarely	Sometimes	Often	Always
1. Ate large snacks	0	1	2	3	4
2. Tried to keep my blood sugar above 150	0	1	2	3	4
3. Reduced my insulin when my blood sugar was low	0	1	2	3	4
4. Measured my blood sugar six or more times a day	0	1	2	3	4
5. Made sure I had someone with me when I go out	0	1	2	3	4
6. Limited my out of town travel	0	1	2	3	4
7. Limited my driving (car, truck, or bicycle)	0	1	2	3	4
8. Avoided visiting friends	0	1	2	3	4
9. Stayed at home more than I liked	0	1	2	3	4
10. Limited my exercise/physical activity	0	1	2	3	4
11. Made sure there were other people around	0	1	2	3	4
12. Avoided sex	0	1	2	3	4

	Never	Rarely	Sometimes	Often	Always
13. Kept my blood sugar higher than usual in social situations	0	1	2	3	4
14. Kept my blood sugar higher than usual when doing important tasks	0	1	2	3	4
15. Had people check on me several times during the day or night	0	1	2	3	4

II. Worry: Below is a list of concerns people with diabetes sometimes have about low blood sugar. Please read each item carefully (do not skip any). Circle one of the numbers to the right that best describes how often in the last 6 months you WORRIED about each item because of low blood sugar.

	Never	Rarely	Sometimes	Often	Always
16. Not recognizing/realizing I was having low blood sugar	0	1	2	3	4
17. Not having food, fruit, or juice available	0	1	2	3	4
18. Passing out in public	0	1	2	3	4
19. Embarrassing myself or my friends in a social situation	0	1	2	3	4
20. Having a hypoglycemic episode while alone	0	1	2	3	4
21. Appearing stupid or drunk	0	1	2	3	4
22. Losing control	0	1	2	3	4
23. No one being around to help me during a hypoglycemic episode	0	1	2	3	4
24. Having a hypoglycemic episode while driving	0	1	2	3	4

	Never	Rarely	Sometimes	Often	Always
25. Making a mistake or having an accident	0	1	2	3	4
26. Getting a bad evaluation or being criticized	0	1	2	3	4
27. Difficulty thinking clearly when responsible for others	0	1	2	3	4
28. Feeling lightheaded or dizzy	0	1	2	3	4
29. Accidentally injuring myself or others	0	1	2	3	4
30. Permanent injury or damage to my health or body	0	1	2	3	4
31. Low blood sugar interfering with important things I was doing	0	1	2	3	4
32. Becoming hypoglycemic during sleep	0	1	2	3	4
33. Getting emotionally upset and difficult to deal with	0	1	2	3	4

NOTE FROM DREXEL UNIVERSITY LIBRARY:

Appendix C is a reference to the Beck Anxiety Inventory, a copyrighted work owned by a third party, and cannot be displayed here.

Appendix D: PTDS (Hypoglycemia)

Briefly describe the most severe or frightening episode of low blood sugar you have ever experienced. Provide as much detail as possible:

_____

_____

_____

_____

_____

_____

_____

_____

Below is a list of problems that people sometimes have after experiencing a traumatic event. *For the following items, please answer each question based on what your experiences were like when you had **an episode of low blood sugar.** Please try to ignore any other events that may influence your answers. Please answer each question based **ONLY on how traumatic having a low blood sugar episode has been and what that experience was like.*** Read each one carefully and circle the number (0-3) that best describes how often that problem has bothered you IN THE PAST MONTH.

0 Not at all or only one time
1 Once a week or less/ once in a while
2 2 to 4 times a week/ half the time
3 5 or more times a week/ almost always

1. 0 1 2 3 Having upsetting thoughts or images **about a low blood sugar episode** that came into your head when you didn't want them to

2. 0 1 2 3 Having bad dreams or nightmare **about a low blood sugar episode**

3. 0 1 2 3 Reliving **a low blood sugar episode**, acting or feeling as if it was happening again

4. 0 1 2 3 Feeling emotionally upset when you were reminded of **a low blood sugar episode** (for example, feeling scared, angry, sad, guilty, etc.)

5. 0 1 2 3 Experiencing physical reactions when you were reminded of **a low blood sugar episode** (for example, breaking out in a sweat, heart beating fast)

6. 0 1 2 3 Trying not to think about, talk about, or have feelings **about a low blood sugar episode**

7. 0 1 2 3 Trying to avoid activities, people, or places that remind you of **a low blood sugar episode**

8. 0 1 2 3 Having much less interest or participating much less often in important activities

9. 0 1 2 3 Feeling distant or cut off from people around you

10. 0 1 2 3 Feeling emotionally numb (for example, being unable to cry or unable to have loving feelings)

11. 0 1 2 3 Feeling as if your future plans or hopes will not come true (for example, you will not have a career, marriage, children, or a long life)

12. 0 1 2 3 Having trouble falling or staying asleep

13. 0 1 2 3 Feeling irritable or having fits of anger

14. 0 1 2 3 Having trouble concentrating (for example, drifting in and out of conversations, losing track of a story on television, forgetting what you read)

15. 0 1 2 3 Being overly alert (for example, checking to see who is around you, being uncomfortable with your back to a door, etc.)

16. 0 1 2 3 Being jumpy or easily startled (for example, when someone walks up behind you)

17. How long have you experienced the problems that you reported above? (Circle ONE)

    1 Less than one month
    2 1 to 3 months
    3 More than 3 months

18. How long after **a low blood sugar episode** did these problems begin? (Circle ONE)

    1 Less than 6 months
    2 6 or more months

Indicate below if the problems you rated before have interfered with any of the following areas of your life DURING THE PAST MONTH. Circle Y for Yes N for No.

19. Y N Work
20. Y N Household chores and duties
21. Y N Relationships with friends
22. Y N Fun and leisure activities
23. Y N Schoolwork
24. Y N Relationships with your family
25. Y N Sex life
26. Y N General satisfaction with life
27. Y N Overall level of functioning in all areas of your life

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Appendix E is a reference to the Beck Depression Inventory, a copyrighted work owned by a third party, and cannot be displayed here.

Vita

Valerie Harwell Myers was born and raised in Fort Worth, Texas by her loving parents. She graduated from Southwest High School in 1992. Ms. Harwell attended Louisiana State University for her undergraduate studies where she majored in psychology and minored in sociology. After graduating with a Bachelors of Science in December 1995, she attended a terminal Masters program at Villanova University. In the fall of 1998, Ms. Harwell began her doctoral training at MCP Hahnemann University which merged with Drexel University in July 2002. She served as a research assistant, clinical trainer, staff therapist, data manager, and project coordinator for a NIH-sponsored study of social phobia in adolescents under the tutelage of James D. Herbert, Ph.D. During her time in Philadelphia, Ms. Harwell obtained extensive clinical and research training at Children's Hospital of Philadelphia under the mentoring of Jerilynn R. Radcliffe, Ph.D., and at the Family Health Psychology Center under the tutelage of Bret A. Boyer, Ph.D. It was through these practica that she developed further her interest in health psychology. In 2001, she earned her Masters of Arts in Clinical and Health Psychology, and in October 2002 began her dissertation research examining mood and anxiety symptoms in adults with insulin-dependent diabetes. In July 2002, Ms. Harwell began her year-long clinical internship at the West Virginia University School of Medicine, Charleston Area Medical Center under the supervision of John C. Linton, Ph.D. During this training year, she obtained clinical training in the areas of cancer, family medicine, cardiac rehabilitation, medical rehabilitation, inpatient/outpatient therapy, and consultation/liaison.

In July 2003, Ms. Harwell married Shane Myers and relocated to Baton Rouge, Louisiana to begin her postdoctoral fellowship at The Pennington Biomedical Research Center of Louisiana State University. Her fellowship includes working on a multisite NIH-study examining weight maintenance interventions after an acute weight loss phase. Additional responsibilities include providing psychotherapy and clinical supervision at the Primary Care Research Center at Earl K. Long Charity Hospital.

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